EXHIBIT 4

UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT
OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File 2:12-MD-0237 MDL 2327
	Joseph R. Goodwin, U.S. District Judge
CAROL JEAN DIMOCK Plaintiff, vs. ETHICON, INC., et al., Defendant.	Case No. 2:12-cv-00401 Videotaped Deposition of: BOBBY LEWIS SHULL, M.D.

March 15, 2016
9:02 a.m.

Location: Beck Redden, LLP
515 Congress Avenue, Suite 1900
Austin, Texas 78701

Reporter: Steven Stogel
Certified LiveNote Reporter, Texas CSR

A P P E A R A N C E S

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ALSO PRESENT: MR. PETER ZIERLEIN, Videographer

I N D E X

E X H I B I T S

P R O C E E D I N G S

(Exhibit No. 1 marked)

THE VIDEOGRAPHER: We are now on the record. My name is Peter Zierlein. I'm a videographer for Golkow Technologies.

Today's date is March 15th, 2016, and the time is 9:02 a.m. This video deposition is being held in Austin, Texas, in the matter of Carol Jean Dimock versus Ethicon, Inc., for the United States District Court, Southern District of West Virginia at Charleston.

The deponent is Dr. Shull. Will counsel please identify yourselves for the record?

MS. THOMPSON: Margaret Thompson for the MDL plaintiffs.

MR. WEBB: Curt Webb for Ethicon.

THE VIDEOGRAPHER: The court reporter is Steve Stogel and will now swear in the witness.

BOBBY LEWIS SHULL,

having been first duly sworn, testified as follows:

EXAMINATION

BY MR. WEBB:

Q. Would you state your full name for the record, please?

A. Bobby Lewis Shull.

Q. Dr. Shull, my name is Curt Webb. We've met

before. Correct?

A. Yes, we have.

Q. And I'm here to take your deposition today in regard to, this morning, two products, Prolift and Prolift+M. Do you understand that?

A. Yes, I do.

Q. Okay. I'm going to show you what's been marked as Exhibit No. 1, which is the notice of your deposition. And once again, you can ignore the Robert on there. But other than that, have you seen this notice before?

A. Yes, sir.

Q. Okay. Dr. Shull, have you brought any documents today responsive to the subpoena duces tecum that's attached to the notice of deposition?

A. Yes, sir.

MS. THOMPSON: And just for the record, we filed objections to the duces tecum request.

A. Yes, sir. I have an updated curriculum vitae. The one which, I believe, was appended to the record you received did not have a list of all my publications, and this one has corrected that omission.

(Exhibit No. 2 marked)

Q. (BY MR. WEBB) So this is an updated current CV that you've given me which I've marked as Exhibit

No. 2 to your deposition. Is that correct?

A. Yes, sir.

Q. All right.

A. I have the general report for Prolift and Prolift+M, and I have a copy of the invoice submitted for the work in preparation for Prolift and Prolift+M.

Q. The Rule 26 expert report that you gave me related to Prolift and Prolift+M, has it changed any since the one that was filed with the Court?

A. No, sir, I don't think it has.

Q. Okay. You've handed me what I'm going to mark as Exhibit No. 3 to your deposition.

(Exhibit No. 3 marked)

Q. (BY MR. WEBB) And this is a three-page document. It looks like the top is a check stub. The second is an invoice. The third is some handwritten notes related to the billing that you've done for the Prolift and Prolift+M general report. Is that correct, sir?

A. Yes, sir.

Q. Would it be fair to state, according to this invoice and the handwritten notes, you had worked a total of just a little bit under nine hours at $650 an hour for a total of 5,740?

A. Yes, sir.

Q. Okay. This invoice runs through January 23rd, 2016. Have you done any work since then?

A. Yes, sir.

Q. How much?

A. I don't know the exact time, but I had preparation for today's deposition, and that required reading my general report again to be familiar with the content and references, and I spoke with Dr. Thompson yesterday about my preparation for today's presentation.

Q. All right. Let's go through that. First off, you read -- in preparation for today's deposition, you read through your general report and just re-familiarized yourself. Is that correct?

A. Yes, sir.

Q. Did you go through any of the medical literature, articles that were referenced in your report?

A. Yes, sir.

Q. And did you read all the ones that are referenced in your report, or did you just read the abstracts, or what did you do?

A. I have a folder that has the information which has been referenced with articles, and I have reviewed each of those articles again, and I have a box to my left which has other documents which were provided to me

with correspondences and with information about Prolift in general, and many, if not all of those, are referenced in the general report.

Q. So you have a binder --

MR. WEBB: And has this information been provided to us by the --

MS. THOMPSON: Yes. And I also have, on a thumb drive, documents provided to Dr. Shull.

MR. WEBB: And does the thumb drive have everything that he's referenced here?

MS. THOMPSON: I believe so.

MR. WEBB: Okay. Well, we'll run --

MS. THOMPSON: Certainly with regard to Ethicon documents it does. He may have some literature of his own. I'm not sure.

Q. (BY MR. WEBB) So you've got a binder that has medical literature?

A. Yes, sir.

Q. Would that be correct?

A. Yes, sir.

Q. And then you have a box of documents --

A. Yes, sir.

Q. -- that were provided to you regarding -- that were Ethicon documents?

A. Yes, sir. And they're here if you would like

to see those.

Q. I'll look at them at the first break.

A. Okay.

Q. Did you meet with anyone in preparation for this deposition today?

A. Yes, sir. I met with Dr. Thompson yesterday afternoon in my home, and I met with her briefly this morning before we arrived for the deposition.

Q. Tell me how long you spent with Dr. Thompson yesterday.

A. Approximately two hours.

Q. And what did you go over?

A. We discussed the format. She wanted to be comfortable that I was prepared and I was knowledgeable about the subject matter to be covered, so we discussed that. We looked at my general report again to confirm that it was accurate.

Q. Anything else in those two hours?

A. Only that we were going to meet here this morning if possible and have breakfast before we came for the deposition.

Q. And did you do that?

A. Yes, sir.

Q. What time did you meet this morning?

A. Probably just a few minutes before 8:00.

Q. All right. Did you discuss anything this morning of a substantive matter?

A. No, sir. Only that we should be here in a timely fashion, and I should have the information that I have supplied to you. She wanted to confirm that I brought that with me.

Q. Anything else that you've done since the invoicing that you've been -- let me just run through this. Exhibit No. 3 has -- it looks to be a check stub. Have you been paid for the $5,740 that you had invoiced -- well, the invoice just says to Margaret.

A. It should have said to Margaret Thompson, and it comes from -- I believe that it states that it was for work done for Prolift. I think it does, but I'm not sure that it does. The stub, I'm talking about.

Q. Well, let me run through them. Exhibit No. 3, you've got a check stub that talks about -- a check stub for 5,740, and there's an invoice dated February 7th, 2016. It says, "Prolift and Prolift+M general report."

The first entry is, "Read draft."

Explain to me why your first entry would be "read draft."

A. I think it must have been -- oh, to read, you're talking about -- I believe the reason it says that is because I had drafted a general report for her

regarding another product in the past, and I wanted to familiarized myself with the format for what was required to put into a draft.

Q. And what product had you prepared a draft report for her -- or had prepared a general report for her in the past?

A. You know, I don't have the exact product name, but I believe it was one for Boston Scientific. But I don't remember the exact product name presently.

Q. I'm just going to read into the record what the invoice says. It says, "January 18, 2016: Read draft, 50 minutes. January 21st: Made corrections, 65 minutes. January 21st: Read reference articles, 190 minutes. January 22nd: Revise general report to reflect supporting articles, 90 minutes. January 22nd: Phone call with Margaret and Meghan, 45 minutes. January 23rd: Confirm accuracy of cited articles and final draft, 90 minutes."

It's a total of 530 minutes, eight hours 50 minutes, a total due -- fee, $650 an hour. Total due, $5,740.

Does that summarize the work that you were doing in regard to preparing a general report for Prolift and Prolift+M?

A. Yes, sir.

Q. Tell me, if you will, how many general reports on how many different products have you prepared in regard to this mesh litigation?

A. I will tell you that I don't know that for certain, but I think there have been two previous general reports, if I'm not mistaken, one on a Boston Scientific product -- and forgive me if I don't remember exactly who made the product, because I may have this incorrectly stated. And I believe that I have done one -- I've done one on Avaulta. Now, I'm trying to remember who the manufacturer for Avaulta is, quite honestly.

Q. So prior to preparing a general report for the Prolift and Prolift+M, you had prepared, you think, two previous general reports?

A. I think that's correct. I know I did Avaulta.

Q. And --

A. I may have done another.

Q. Okay. Who else did you -- who did you work with in preparing those general reports for the two -- the two previous general reports that you think that you prepared?

A. Dr. Thompson, primarily.

Q. We're here today to talk about, in this deposition, the -- your opinions with respect to Prolift

and Prolift+M. Correct?

A. Yes, sir.

Q. You've given opinions in the past with respect to Prolift and Prolift+M, haven't you?

MS. THOMPSON: Object to form.

A. In a general report? Are you asking me about that?

Q. (BY MR. WEBB) In depositions for these products.

MS. THOMPSON: Same objection.

A. I gave depositions last week with you for two women who had had Prolift products.

Q. (BY MR. WEBB) Okay. Is there anything about the prior testimony, after reviewing the report and reviewing the literature, that you want to correct for the depositions that we gave regarding Prolift and Prolift+M?

A. No, sir, I can't think of any.

Q. You also have prepared a general report on another product -- Ethicon product, Prosima?

A. Yes, sir.

Q. And as we walk through these reports today, your opinions are mostly identical for each of these products -- Prolift, Prolift+M, and Prosima -- except that where you characterized them differently in the

report. For example, there will be paragraphs that are identical as we walk through these reports. Is that correct?

A. Some things will be similar and some will vary depending on -- excuse me -- the scientific literature. Some of the internal documents will be the same, and some of the descriptions of my concerns will be the same.

Q. Okay. Do you have any kind of a written agreement between Ms. Thompson and yourself about -- or the law firm that she represents or the various law firms about what you will do as far as the work that you'll be doing in this mesh litigation?

A. No, sir. Everything has been oral.

Q. Are you required to bill anyone else for general work that you do on these products other than Ms. Thompson?

A. No, sir.

Q. Is the totality of the universe of which you've reviewed the medical literature that you have in front of you and the box of documents -- the Ethicon documents that you have?

MS. THOMPSON: Object to form.

A. These articles that I have in my own possession that I've used previously for work, for

journal club, and for teaching and whatnot may not be in this binder. And I have read those in preparation for today, not specifically for one deposition or the other, but I read them in general. So here are three articles which I brought.

And I'm not sure -- one of them may already be in the binder. I'm not positive that all three are.

Q. (BY MR. WEBB) The material in the binder, did you locate this material yourself, these medical articles, or were they given to you?

A. It was a -- this binder was given to me, but of these things that are in the binder, I would say the vast majority I was familiar with already in my role as a teacher and participant in various things. So this was organized and sent to me.

Q. Okay. And it was sent to you by plaintiffs' counsel?

A. Yes, sir.

Q. All right. So you've given me three articles, the top one labeled "Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with Prolene mesh," which was in "BJOG" -- "BJOG: An International Journal of Obstetrics & Gynaecology" dated January of 2005. And it's marked up and has handwritten

notes on those.

Are those your notes?

A. Yes, sir.

Q. Okay. The second one is "Defining success after surgery for pelvic organ prolapse," and it's in "Obstetrics and Gynecology," Volume 114, No. 3, September of 2009, and once again has handwritten notes and markups on it.

Are those your handwritten notes and markups?

A. Yes, sir.

Q. The final is an article titled "Host response after reconstruction of abdominal wall defects with porcine dermal collagen in a rat model", American Journal of Obstetrics and Gynecologist," 2004. And once again, it has highlighting and markups on the document.

Are those your highlighting and markups?

A. Yes, sir.

Q. And these are articles that generally you had in your possession that you used for your own education or for -- to teach. Is that correct?

A. Yes, sir.

MR. WEBB: Let's go off the record for a minute.

THE VIDEOGRAPHER: Going off the record,

the time is 9:22.

(Recess from 9:22 a.m. to 9:34 a.m.)

THE VIDEOGRAPHER: Back on the record, the time is 9:34.

Q. (BY MR. WEBB) Dr. Shull, you told me you've got a binder that's in front of you.

A. Yes, sir.

Q. If you could hold that up just so it will be on the screen.

That's a binder that was provided to you that has the articles -- the medical articles that were sent to you by plaintiffs' counsel for you to review in preparation for making your general report for the Prolift and the Prolift+M, correct?

MS. THOMPSON: Object to form.

A. Yes, I used these articles in the preparation.

Q. (BY MR. WEBB) And to your left there's a box that has a number of folders in it that contain documents that were produced by Ethicon. Do you understand that to be what those are?

A. Yes, sir.

Q. And in that box, there is everything from medical articles to email correspondence to marketing materials, just a variety of different materials. Is that correct?

A. Yes, sir.
Q. And I would say it's not quite a box full, maybe about half a box. Would you say that's about --
A. Yes.
Q. -- right?
A. Yes, sir.
Q. A banker's box. If I look at your bill -- and this is the only bill that you submitted for Prolift and Prolift+M in preparation of your general report. Is that correct?
A. Yes, sir.
Q. And so it would basically entail all the time you spent reading all the articles, going through all the documents, and preparing your general report and working with plaintiffs' counsel in order to finalize that general report?
A. Yes, sir.
Q. Okay. So the first entry, 50 minutes of reading draft, you think that may be a prior general report that you did just to get the format down?
A. I think that's part -- excuse me. I'm losing my voice. It's part of it, to get my thoughts organized about what is expected in a report by looking at something that had been done previously and organizing my notes on what I could do on this particular report.

Q. There is an entry for read referenced articles, 190 minutes. Does that entail both the binder full of medical literature that's in front of you and the box of Ethicon documents?

A. I would have to look at that and see if there was anything else mentioned. I actually didn't commit this to memory. Yes, sir, I think so.

Q. Tell me how many medical articles are in that binder that are in front of you.

A. I didn't count them, but I can do that.

Q. Just a rough estimate, as you look at them.

A. 20 or 25.

Q. As I went through the box with the Ethicon documents in them, those are not documents you requested. Those are documents that were forwarded to you that plaintiffs' counsel thought might be helpful in preparing your general report. Would that be a fair statement?

A. Yes, sir.

Q. Did you go through those documents and request other documents based upon what you saw in the documents that had been sent to you?

A. I don't recall requesting another document.

Q. As I went through, for example, I noticed that there were some handwritten notes in pen and there was

some highlighting. Did you go through and make those handwritten notes and highlighting as you looked through the documents?

A. Yes, sir.

Q. There were at least four folders that had portions of deposition transcripts. Did you request those deposition transcripts, or were they sent to you by plaintiffs' counsel?

A. They were sent to me by plaintiffs' counsel.

Q. For example, I have one here that's the transcript of deposition of Giselle -- is it Bonet, B-O-N-E-T?

A. Yes, sir, that may be the way you pronounce it. I don't know that.

Q. All right. Taken March 5th, 2012, and there's -- that's the cover page. There's one other page here in this, and it's Page 102. Was that -- for the portions of depositions that were given to you, was that all that was given was just selected portions of those depositions?

A. Yes, sir.

Q. Did you ask for the full transcript of the deposition in order to put them in context?

A. No, sir.

Q. So, for example, in this deposition, for

whatever reason, you were given one page, Page 102, out of however many pages were in this deposition?

A. Yes, sir.

Q. And the reason that you have it marked is there's a handwritten note that said, "Kit not studied." What does that mean?

A. May I see it?

Q. Sure.

A. And I'll tell you.

At the top of Page 102 in the deposition, Giselle Bonet, the question was, "At the time the Prolift, which is trademarked, was launched, the Prolift itself had not been studied in clinical studies, correct, meaning the actual packaged product with the preformed mesh and the instruments had not been studied clinically?"

So the person doing the deposition asked that question of Giselle Bonet, and her response was, "That's correct. The kit had not been studied."

So the reason I made this note is to remind me that Prolift was marketed without any clinical testing.

Q. Do you know whether or not there was any discussion of any other clinical testing anywhere in this deposition? Do you have any idea?

A. No, sir.

Q. So all you know is based upon the one page that you were provided out of whatever number of pages that was in that transcript?

A. For that particular folder, that's correct.

Q. The next folder we're going to look at is a folder marked "Kirkemo, Aaron," of a deposition taken April 18th, 2012, and it entails one, two -- six pages of a deposition, and it's highlighted.

Did you look at this deposition and make the highlighting that's on the deposition portions of the deposition that were provided to you?

A. Yes, sir, I did.

Q. Okay. Once again, did you ask for these portions to be sent to you, or was that just sent to you by plaintiffs' counsel?

A. This was sent to me by plaintiffs' counsel.

Q. Did you request the entire deposition so you could read it all and put it in context?

A. No, sir, I did not.

Q. Page 1 is the cover page. The next labeled page is 135, 136, 137, 138, and then it skips to 150.

Do you have any idea how long this deposition was?

A. No, sir.

Q. The next deposition, the name on it is Hinoul, H-I-N-O-U-L, P-I-E-T, dated April 6, 2012.

Once again, was this portion of a deposition transcript provided to you by plaintiffs' counsel?

A. Yes, sir.

Q. Did you ask for the entire deposition so you could put it into context?

A. No, sir.

Q. It has two pages, the first page is Volume 2 -- or it's a cover page for Volume 2, which is marked Page 351, and the one page actually has four pages from the deposition on this one-page transcript -- from the transcript. Those are labeled Page 504, 505, 506, and 507.

Did you ask for the entire deposition in order to put this in context?

A. No, sir.

Q. And the final one that I found in the box that you had that had been provided by plaintiffs' counsel is a deposition taken of Scott Hamilton Jones dated January 25th, 2012. This is Volume 3, Page 654, and there are three actual pages of deposition testimony from Page 727, 728, and 729.

Did you request these pages specifically?

A. No, sir.
Q. Did you ask for the entire deposition so you could put it into context and see if there was anything else that was significant?
A. No, sir.
Q. Were you given any complete transcript of any deposition that's been taken in any of the mesh litigation by plaintiffs' counsel in preparation for doing your general report for Prolift and Prolift+M?
A. No, sir.
Q. Have you ever made any request for any Ethicon documents that have not been provided to you?
A. No, sir.
Q. One of the things that we asked in the subpoena duces tecum was a list of the cases. Have you provided a list of all the cases that you have --
A. Yes, sir. I thought that was appended. If it isn't appended to that --
Q. Appended to your general report?
A. Yes, sir. If it isn't appended to that -- this is for later when you ask me about Prosima. I actually thought both of them had something, but maybe that one doesn't have it. It wouldn't be behind my curriculum vitae. It would be behind the general report. But this would be the one that would be similar

for both of them. Yes, sir.

Q. Okay. And the request -- what I have for you, other than the depositions that were taken last week in case-specific matters, does this list that's appended to your expert report, your general report, is it a complete list other than the ones we had last week?

A. The only thing I see differently, now that you've asked me specifically about it, is last week when you deposed me, I told you there was one person's name on the list, Mrs. Rabiola, R-A-B-I-O-L-A, and I was deposed because I was a treating physician for her. I wasn't deposed --

Q. As an expert?

A. No, sir.

Q. Testifying expert?

A. No, sir. Josephine Rabiola. And I just see that this isn't on this, and I'm not certain why. But you and I talked about that last week, that I was a treating physician for her.

Q. When were you first contacted by anyone in regard to giving expert testimony in regard to Prolift and Prolift+M products?

A. I don't have the exact date, but it would have been sometime in the last quarter of 2015. I believe that would be correct. I was asked if I would do it,

and I was given a potential window of time that the work would need to be performed, but it wasn't immediate at the time that I discussed it with Dr. Thompson.

Q. Was she the individual that contacted you?

A. Yes, sir.

Q. And when you say Dr. Thompson, are you referring also to the lawyer that is presenting you for deposition today?

A. Yes, sir, Dr. Margaret Thompson, who is also an attorney.

Q. What did she ask you to do?

A. She asked me to work with her on preparing a general report about the products Prolift and Prosima.

Q. Any other work that she asked you to do?

A. Not specifically at that time, no, sir.

Q. Okay. Give me a ballpark, if you will, on how much you've earned in this litigation since you were first contacted by Dr. Thompson up to the current -- and I understand you haven't invoiced for everything. You invoiced for individual cases. But just generally give me an idea if you can, Doctor.

A. Well, I think -- yes, sir.

MS. THOMPSON: Object to form.

A. Yes, sir. I think last week on the case-specific report, I submitted the invoices to you.

Honestly, I don't know the exact amount, but I would say it was approximately -- it may have been 26 or $28,000. I don't know that. Maybe that's high. I don't remember that exactly, to be quite honest with you. There were three cases -- that's not correct. It probably was 15 or $20,000, actually.

What I told you was incorrect because there were three case specifics. And I think each was five or so thousand dollars, so it was probably 15 or so thousand dollars.

Q. (BY MR. WEBB) So would you say -- if we tried to approximate not only the case-specific work that you've done, but also the work on Prolift and Prosima, that -- generally we could say it's under $50,000, roughly?

A. Yes, sir.

Q. Okay.

A. At this point, it's probably closer to 25 or $30,000.

Q. Okay. So 25 or 30 would be a better estimate in your mind --

A. That would be the two general reports and the three case-specific reports.

Q. And does not include the time that you spent that you didn't invoice for for last week for the

depositions and the preparation and deposition time today?

A. Yes, sir, that's correct.

Q. When you have a patient that comes in that has a mesh product already implanted in that patient, do you inform them that you are a plaintiff -- that you're an expert for the plaintiffs in this mesh litigation?

A. I don't think that's ever come up, no, sir.

Q. When you draft these reports, were you given a template to go by in order to lay out the format that you should prepare your expert report in?

MS. THOMPSON: Objection to questions about the drafting of the reports.

A. Well, I have to --

MS. THOMPSON: And anything that goes too much beyond this, I'm going to instruct him not to answer.

A. I have to have some idea about what is reasonable from a legal standpoint, because that's not in my normal area of knowledge, so I have to have some guidance about how to construct a report, if that's what you're asking me. I've spoken with Dr. Thompson about what would be a reasonable format to present that is a fair assessment of my own observations and is something that would be expected in a legal proceeding.

Q. (BY MR. WEBB) Prior to getting involved in this mesh litigation, had you ever prepared an expert report for any expert testimony that you had given in any litigation?

A. No, sir.

Q. As we go through your expert report, which we will do, there are medical literature that are summarized -- would that be a fair statement -- in your expert report?

A. Yes, sir.

Q. Do all of these articles that are listed in your expert report for Prolift and Prolift+M, did they come out of that binder that was provided to you by plaintiffs' counsel?

MS. THOMPSON: Object to form.

A. I believe that's correct.

Q. (BY MR. WEBB) Did --

A. I believe that's accurate.

Q. Okay. Did you put in any article or any abstract that you found on your own that was not provided to you by plaintiffs' counsel?

MS. THOMPSON: Object to form.

A. That is referenced in the general report? Is that what you're asking?

Q. (BY MR. WEBB) Correct.

A. To the best of my knowledge, I did not.

Q. Did you go do a review of the medical literature to see if there were articles that showed different results from the articles that you -- were given to you by plaintiffs' counsel?

MS. THOMPSON: Object to form.

A. Well, if you're asking me is this the only literature I'm familiar with, the answer is, no, it isn't.

And are there articles that I have read that aren't in this? And there are.

My -- part of my responsibility in reviewing the available articles is to look at the scientific approach that was taken and then review the conclusions because, in many articles, there are -- there would be more than one way to interpret the outcome.

So my job is to look at that and try to determine is there some other message in these articles that might be helpful in reaching a decision about the -- in this case, the products which are being reviewed, Prolift and Prolift+M.

MR. WEBB: Object to responsiveness of the answer.

Q. (BY MR. WEBB) The question I asked: Did you

do any independent research and go find any other medical articles other than the ones that were provided to you by plaintiffs' counsel?

A. Yes.

MS. THOMPSON: Object to form.

A. Yes, sir. I subscribe to multiple journals and review them on a regular basis, and not everything I reviewed is in here.

Q. (BY MR. WEBB) No. The question is: Did you go do -- when you were preparing your general report for Prolift and Prolift+M, did you go find any article and use that article and abstract it or summarize it in your general report other than the ones that were provided to you in that binder?

MS. THOMPSON: Object to form.

A. I don't think I found any different than what I have. I think everything I have is here.

Q. (BY MR. WEBB) Dr. Shull, the question is: Did you go do any independent research and pull any other article other than the ones that had been provided to you for use in preparing your general report?

MS. THOMPSON: Object to form.

A. Well, I think what was provided is what I asked for. So part of what I asked for would be in here. I don't know how to answer that any more clearly.

Q. (BY MR. WEBB) Listen to the question, then. My question is: Did you go and do some independent research and pull an article from a medical journal and use it in your general report other than the articles that were prepared and sent to you by plaintiffs' counsel?

MS. THOMPSON: Object to form, now asked and answered.

A. Well, I will answer that. These came partly from my request and partly what was given, so I asked for part of these. So the answer is I didn't have anything that isn't in here, but these weren't all spontaneously given to me. I requested some of these. And I gave you copies of a couple of things otherwise that aren't in here that specifically I did look for. I mean, at the beginning, I gave you those, for example.

Q. (BY MR. WEBB) The three articles that you gave me before, are any of those three articles summarized in your general report on Prolift or Prolift+M?

A. No, sir. The background knowledge of it is, though. The concepts are. For example, what is a successful outcome of surgery, which is one of the ones I think that's on the top -- or is in that stack of three, how do you assess the outcomes of surgery.

Q. And that's fair for your general background knowledge that you used to develop an expert opinion, but you actually went through and abstracted or summarized articles in --

A. Yes, sir.

Q. -- your general report. Are any of these three articles abstracted or summarized in your general report?

A. No, sir.

Q. You state in your expert report on Prolift and Prolift+M that you have seen -- you have personally examined, diagnosed, and treated approximately 100 patients with mesh complications and removed some mesh from at least 70 women. Is that correct?

A. Yes, sir.

Q. Have you prepared any type of formal report or summary of the complications you have seen? Have you submitted it to any peer-reviewed medical journal for publication?

MS. THOMPSON: Object to form.

A. The one that's --

MR. WEBB: Wait a minute. What's the problem with that?

MS. THOMPSON: It was compound.

MR. WEBB: Read the question.

MS. THOMPSON: "Have you prepared any type of formal report or summary of the complications that you've seen? Have you submitted it to any peer-reviewed medical journal for publication?"

MR. WEBB: You think that's compound?

MS. THOMPSON: Well, I think there are three questions in there.

MR. WEBB: All right. Let's break it down.

Q. (BY MR. WEBB) Have you prepared any kind of formal report based upon the summary -- based upon your examination and treatment of these 100 patients?

A. I have one case report. I don't have a summary of all of them.

Q. Okay. Have you prepared any kind of article and submitted it to any medical journal summarizing the treatment of these patients that you've seen?

A. No, sir. Only the one that was a case report.

Q. And have you submitted any complaints or made any complaints to the FDA about any of the products that you saw in these patients who you have treated?

A. We have a fellowship program, so we educate other people who are going to have skills in the subset of female pelvic medicine, reconstructive surgery. So our fellows have reported a few of these, but certainly

not all of them. But I personally have not done that. They've done it at my request.

Q. You've reported complications that you've seen in patients to the FDA not personally, but you've had some of your fellows make those reports?

A. Yes, sir.

Q. Okay. Have you -- were those reports made prior to you signing on as an expert for the plaintiffs in this mesh litigation or after?

A. It was before. This was early on -- excuse me. This was early in our experience.

Q. When did you first start seeing patients that had complications with mesh? You said you've seen about 100?

A. Yes, sir.

Q. When would have been the first one?

A. You know, I don't know the exact date, but I'm going to say in the neighborhood of 2004 or '5.

Q. Okay.

A. Because when I say I've seen complications, it has meant suburethral slings, it has meant mesh implanted for prolapse, it has meant abdominal sacrocolpopexy. So it's all of those things, including mesh for transvaginal reconstructive surgery. So somewhere in the range of 2004, 2005.

Q. And what you're telling me is this is a range of all mesh products over a period of -- when is the last time you saw someone that had a problem?

A. You know, probably in the end of calendar year 2015.

Q. So roughly, you would say, a ten-year period?

A. Yes, sir, more or less.

Q. And in that ten-year period, you've seen approximately 100 women who you say had a variety of different products across the spectrum of the surgeries that use gynecological mesh for repair of various problems?

A. Yes, sir.

Q. Okay. How many of that 100 were either Prolift or Prolift+M?

A. You know, I don't know the exact answer to that because some patients don't know for certain which product was used, and we don't have the operative note. In some of them I did know that for a fact.

So some of them, including the case report we gave, which is in my bibliography, is specifically Prolift. Yes, sir. And this would be the tension-free vaginal tape, the article you've referenced here.

Q. Is that the case report you're talking about?

A. Yes, sir. There is -- no, sir. This is not the one I was referring to. This is one using tension-free vaginal tape for urinary incontinence.

The article I was referencing is one on erosion of a Prolift into the rectum, and one of our fellows reported on one other patient -- Dr. Chris Chung reported on a patient, and I'm not sure if that's in my bibliography or not, because some of the things the fellows do I would have participated in the publication, and some of them I wouldn't have.

(Exhibit No. 4 marked)

Q. (BY MR. WEBB) I've marked as Exhibit No. 4 a case report titled "Tension-free vaginal tape bowel perforation."

A. Yes, sir.

Q. And this is in the International Urogynecological Journal of 2010. Is that right?

A. Yes, sir.

Q. And you were one of the authors on this case report?

A. Yes, sir, that's correct.

Q. This case report has nothing to do with either Prolift or Prolift+M, does it?

MS. THOMPSON: Object to form.

A. It does not.

Q. (BY MR. WEBB) And, in fact, in this case report what you're actually reporting on is a problem where there was a perforation of the bowel due to the technique of the physician?

MS. THOMPSON: Object to form.

A. This article on tension-free vaginal tape bowel perforation refers to a technical issue with placement of a retropubic tension-free vaginal tape, and the bowel was perforated by the trocar.

Q. (BY MR. WEBB) And actually the tape was actually placed through the bowel. Is that correct?

A. Yes, sir, that's correct.

Q. You told me that you think that some of the 100 women that you saw had Prolift or Prolift+M. Can you give me an approximation of how many of those patients had Prolift or Prolift+M?

A. I can --

MS. THOMPSON: Objection; asked and answered.

A. Yes, sir, I could do that, but I can't validate it.

I know there have been -- I know for a fact there have been at least two patients -- because I remember them -- who knew the product, and it was Prolift. There may be others, but I didn't go back in

preparation for today to look at that and try to abstract that information from the records.

Q. (BY MR. WEBB) Did you do a specific literature search -- medical literature search for either complications related to Prolift or complications related to Prolift+M products?

A. In preparation for this general report, you're asking?

Q. For any reason at all, but especially in representation for this general report?

A. Well, not specifically in preparation for this report. I've looked at that previously, but, no, I didn't for this.

Q. When did you look at it?

A. Oh, I can't give you a specific date. Again, in the education of other people, it's a part of what we do is to review literature and discuss it. So I don't have the exact date for that.

Q. Have you ever personally used either Prolift or Prolift+M in any type of surgery?

A. No, sir.

Q. Have any of your people that work in your practice, the other physicians that are in your practice, do they either use Prolift or Prolift+M for surgery?

A. There are four of us -- excuse me -- in our department who see women with disorders of the pelvic floor. Two of us, I feel certain, have not used Prolift products. I know that I haven't, and I believe that Dr. Paul Yandell has not.

We have two other colleagues who received as part of their education and/or practiced elsewhere before they came to work for us, and these two individuals, I could not tell you whether or not they've ever used Prolift or Prolift+M elsewhere.

To the best of my knowledge, they have not used it while working in our department.

Q. When you do training, do you -- have you ever done any training with Prolift or Prolift+M products?

A. You mean in being taught myself or in teaching someone else?

Q. Both.

A. No, sir.

Q. Have you ever involve -- been involved in any clinical study involving pelvic mesh products in general?

MS. THOMPSON: Object to form.

A. No clinic study. Our research group studied Pelvicol in an animal model, but we haven't had a clinical study of any product.

Q. (BY MR. WEBB) If we go through your bibliography, have you written articles on urinary incontinence?

A. Yes, sir.

Q. And pelvic organ prolapse?

A. Yes, sir.

Q. Any articles on surgical mesh?

A. Only these case reports and an editorial. But I didn't do a scientific report on mesh, but there's an editorial with Dr. Linda Brubaker. I believe it was published in either 2011 or 2012.

Q. Have you ever written any kind of scientific report or medical article in the peer-reviewed literature related -- about how to remove pelvic mesh products?

A. No, sir.

Q. When you did any explantation of any mesh product, have you done -- has all the mesh product that you have had explanted been sent to pathologists for review?

A. Yes, sir, to the best of my knowledge, it has been. I mean, it's entirely possible that I removed -- let's use, for an example, a piece of a midurethral sling that was visible and I could measure it and comment on it, and there was no gross evidence of

anything other than it was exposed, I may not have sent that to pathology, but I wouldn't know how to go back and learn exactly how often that would have happened.

Q. Has there been any evidence in any of the pathology reports that you received that indicated any type of degradation or breakdown of any of the surgical mesh?

A. In our particular organization, what we would normally receive as a report is a confirmation that a sample had been submitted. Usually the dimensions would be included in number of centimeters in length and width. Sometimes it's just a gross description that the pathologist confirmed that we submitted something that was a particular size and it had other tissue attached to it.

Sometimes it would be a microscopic evaluation, but not always. And the microscopic examinations, I think it would be exceptional that I would have received a report that commented on degradation.

Q. Can you remember, as you sit here today, ever receiving a report that commented on degradation?

A. I'm not sure that I have. If I had to guess, I would say I probably have not.

Q. Do you believe it's below the standard of care

to use transvaginal mesh implants?

MS. THOMPSON: Object to form.

A. Surgery is a job, and it is like, I think, practically every job else, there are more -- there is more than one way to accomplish what you are going to do. I personally have chosen not to use mesh products for transvaginal repair for prolapse. Other people do, and I'm not suggesting that's below the standard of care, but it's an option. It's an option that I haven't chosen.

Q. (BY MR. WEBB) You've done some rabbit studies?

A. Yes, sir, the people in my research group. I don't think my name was on the article, but they implanted Pelvicol in the vaginal canal of rabbits and reported on the response to the Pelvicol.

Q. Does it have anything to do -- that bears directly on this litigation?

A. No --

MS. THOMPSON: Object to form.

A. There was no comparison with Prolene, for example, so we did not use a Prolene product.

THE REPORTER: A Prolene what?

THE WITNESS: A Prolene product.

THE REPORTER: Thank you.

Q. (BY MR. WEBB) From your review of the Ethicon literature, what stages of pelvic organ prolapse would Prolift and Prolift+M be used to treat?

MS. THOMPSON: Object to form.

A. When I --

MR. WEBB: On what basis?

MS. THOMPSON: "Ethicon literature." Does that mean Ethicon sponsored? Ethicon published?

MR. WEBB: Forget it.

Q. (BY MR. WEBB) Go ahead.

MS. THOMPSON: I just don't understand --

MR. WEBB: Forget it.

MS. THOMPSON: -- "Ethicon literature," what that means.

Q. (BY MR. WEBB) Do you understand what "Ethicon literature" means?

A. If you mean the information for users, for example, I think I can comment on that.

Q. Can you also comment on all the Ethicon documents that you were provided in the emails -- the general -- any question about any Ethicon document or literature that you reviewed, can you tell me, based upon that, what stages of POP would use either Prolift or Prolift+M to treat?

A. I would say, in general, what I think I can

glean from that is if the patient were symptomatic, and that then doesn't lend itself to a quantification of any kind, but if a woman has symptomatic -- excuse me -- pelvic organ prolapse, they may be a candidate.

But in terms of assigning that to a particular stage or grade or degree of prolapse, I don't believe that I have seen that in any of the literature.

Q. Based upon prior depositions and your opinions that you provided, you prefer the use of native tissue in your surgeries for prolapse. Is that correct?

A. Yes, sir.

Q. You belong to a number of different professional societies that specialize in this area. Would that be a fair statement?

A. Yes, sir.

Q. And as any specialist, there's a limited horizon of people that both have the experience and belong to those professional societies. Would you agree with that?

A. Yes, sir.

Q. Is there any consensus among the specialists in these gynecological societies that you belong to, or urogynecological societies that you belong to, about whether there are benefits that outweigh the risks or risks that outweigh the benefits of the use of

transvaginal mesh?

MS. THOMPSON: Object to form.

A. When I -- excuse me -- referred to the article that I handed you by Dr. Barber and his associates about assessing the outcomes of surgery, in -- I want to apply it to these groups.

So the groups that I belong to who are interested in caring for women with pelvic organ prolapse have been looking primarily for an improvement in the anatomical outcomes of surgery for poor support.

And as I understand it, I believe there is a consensus that surgery of any kind doesn't work for all people all the time. And if we could do something to reduce the failure with anatomical outcomes, that would be desirable.

And one of the thoughts about using any product, whether it's biological or synthetic or autologous or xenograft is to try to improve on those anatomical outcomes.

So in that broad context, I think people agree that that's a laudable goal. And then the question where their ideas diverge is how do you go about learning about that.

So once -- I think under ideal circumstances, most people would say, "We would like to

have as much scientific information as we can that something is not only effective but that we know about the other parameters, including possible injuries or side effects associated with it."

And so that's what people would like to know. I think everyone would like to know those things.

In terms of which method of approach for surgery, as I alluded to earlier, surgery is a job, and not everyone is going to choose to do the same thing. For example, some people are very technically skilled with abdominal sacrocolpopexy, and that may be their operation of choice. Other people may be very skilled vaginally, and that may be their operation of choice.

And there's another group of people who may be skilled in either one of those who feels that maybe using a mesh -- synthetic mesh complement to their surgery would be beneficial. So we certainly fall into those different groups. And once we get to there, I don't think there's a consensus.

Q. (BY MR. WEBB) Okay. You will agree that there are good doctors on both sides of this debate -- or all sides of this debate?

MS. THOMPSON: Object to form.

A. I believe that there are honest people raising these questions and wanting to do what's best for the

patient.

Q. (BY MR. WEBB) In your report on Prolift products, you cite a recent report by Stanford stating that most studies shows an anatomic success rate of about 92 percent for mesh. Do you remember that --

A. Yes, sir.

Q. -- statement?

A. Yes, sir.

Q. Do you agree with that statistic you cited?

A. Well, I have the article here referenced in front of me, and I believe in his assessment of the literature that there are varying reports on the anatomical outcome.

So when anatomy is the primary endpoint of the outcome, that's a fairly well defined issue. The -- I'll just say in general, the area of confusion about anatomy is not that it's evaluated, but we don't know what is a reasonable anatomical outcome to expect in a woman of various ages.

For example, women who are 18 or 20 who have never had a baby or have never been traumatized in any way may have one set of physical exams which we could describe, and under ideal circumstances, maybe we could recreate that with surgery, but that isn't what most people have. So that may not be a realistic

anatomic outcome.

What is -- I believe most doctors have now come to a consensus about is a good anatomical outcome is one in which no compartment of the vaginal canal, either anterior or posterior, prolapses outside the hymen, the opening to the vaginal canal. When we use that as an endpoint, all of the surgical outcomes appear to be better.

When we're more rigid -- whether it's mesh or not mesh, when we're more rigid, the unsatisfactory outcomes from the standpoint of just looking at the anatomy are greater.

What Dr. Barber's article points out is it isn't only anatomy. It's also the patient's perception of what's going on, and it's did they require more intervention. So he has those three parameters.

And when you look at all three of those parameters, each of these authors, I believe, would report that the outcomes of surgery are better than when you have rigid anatomic outcomes. That's been an evolution in our reporting system -- actually, a good evolution.

Q. Are you personally critical of all uses of a polypropylene mesh for pelvic reconstruction?

A. I haven't chosen to use it. If you're asking

me am I critical of using it for everybody under every circumstance, that's an individual decision for each doctor and patient to make.

In my own personal experience, I am not convinced that given my ability to accomplish what I want to accomplish technically, that the benefits of adding a polypropylene mesh is greater than the side effect. So in my own hands, I have chosen not to do that.

Q. You have associates in your own practice, though, who perform sacrocolpopexy using polypropylene mesh. Right?

A. Yes, sir. Through the abdomen, they do. And we use it in the suburethral slings. So each of us have used these midurethral slings, which are made of polypropylene.

The area where I think we are less likely and perhaps haven't used mesh in our institution is for transvaginal repair of prolapse.

Q. And the product that your associates use and the product that you use for the suburethral slings is usually an Ethicon product?

A. Yes, sir. And some of that depends on what the organizational purchase is, because all organizations now are trying to bring standardization to

the purchases. So we have used some other products, but I would say the preponderance of what we use has been from Gynecare, J&J. I'm sorry. My voice is --

MR. WEBB: Let's take a little break, give you a chance to get some water.

MS. THOMPSON: I was just --

THE VIDEOGRAPHER: Going off the record --

THE WITNESS: Thank you.

THE VIDEOGRAPHER: Going off the record, the time is 10:26.

(Recess from 10:26 a.m. to 10:43 a.m.)

THE VIDEOGRAPHER: Back on the record. This marks the beginning of Disc No. 2. The time is 10:43.

Q. (BY MR. WEBB) I'm going to walk through some of the opinions that you expressed related to the Prolift and Prolift+M devices --

A. Yes, sir.

Q. -- for pelvic organ prolapse.

Your first opinion is, "At the time of introduction, there was insufficient scientific evidence supporting the implantation of the Prolift and Prolift+M devices for pelvic organ prolapse."

What type of scientific evidence are you

referring to here?

A. I found no evidence that the product consisting of the mesh with the attached trocars had been used in women in a systematic fashion with information collected about the morbidity, the anatomic outcomes, and the potential for risk associated with this specific kit of the Gynecare mesh, Gynemesh, and the trocars, which is how Prolift was marketed.

Q. The individual mesh had been on the market for other uses for a number of years. Would you agree with that?

A. Yes, sir.

Q. The trocars, were there anything unique or special or brand new about those?

MS. THOMPSON: Object to form.

A. The trocars in and of themselves, to the best of my knowledge, are not unique. The use of the trocars to penetrate spaces in the pelvis and then to deploy the mesh arms into those spaces, in fact, was a new concept.

Q. (BY MR. WEBB) So it's not the complaint about the kit being unique or special. It's the technique that was used to place the mesh in the woman's body. Is that correct?

MS. THOMPSON: Object to form.

A. As I understand it, from my review of the

literature, Prolift used the Gynemesh, which you indicated had been on the market previously. What was new was the concept of a product using the trocars and deploying the mesh arms into muscle, connective tissue, through the skin of the vagina and the external skin in living people. That was a new concept. And I could not find any information that there had been an objective trial of that before the product was actually used.

Q. (BY MR. WEBB) Do you know whether or not -- when you say an objective trial, do you know what the company had done as far as working with surgeons, working with providing -- learning the techniques that need to be used and teaching those techniques to physicians prior to it being implemented for commercial use?

MS. THOMPSON: Object to form.

A. What I understand or what I glean from the literature is Dr. Jacquetin in France and Dr. Cossan, C-O-S-S-A-N, and a group of French surgeons worked to develop the concept of an American product being deployed into the pelvis, and a lot of the original observations were made with that French total vaginal mesh group. So I did see that.

Q. (BY MR. WEBB) Well, do you know what kind of protocols or what kind of scientific basis that the

initial users of the product had or put in place before they started using this product in patients?

MS. THOMPSON: Object to form.

A. What I know is they evaluate the patients for prolapse in advance of surgery, what site in the pelvis had poor support, and what degree of poor support that those sites had. And they then looked at the technical feasibility of placing the trocars into the pelvis and deploying the mesh, and subsequently followed some of the patients for a period of time to look at the anatomic outcomes.

They then solicited opinions, observations from clinicians on concerns about the technical aspects of using the product, unknown concerns that these physicians had heard from their patients regarding either favorable or unfavorable outcomes from the use of the product.

Q. (BY MR. WEBB) And is this, in your opinion, a deviation from the norms in how you develop a new product for use in patients?

MS. THOMPSON: Object to form.

A. Well, in this particular circumstance, counseling a group of patients to participate in a scientific trial and informing them of the risks and benefits would be a helpful thing to do, understanding

that it's not possible to give full disclosure because the trial is intended to learn about the potential benefits and risks of the surgery.

So that would have been a helpful thing to do. And then limiting the use of this product to a defined group of people until there was adequate information to make, if necessary, modifications in the indications and use of the product to learn how to avoid complications when possible and to learn how to manage them if and when complications occur.

So that would have been an ideal set of circumstances in a defined group of physicians and surgeons and a defined group of patients, followed by a long enough time period to be able to provide that information.

Q. (BY MR. WEBB) Do you know whether or not the patients in this initial group that were -- the French surgeons used were provided -- what kind of informed consent they were provided?

A. Some of them -- I don't know all of them. Some of them actually were provided information that they were collecting data on the -- on this technique.

Q. Do you know whether or not those physicians followed these patients long term?

A. Well, initially they could only have followed

them for -- in some cases, some of the earlier reports were a matter of three to six months. Some were perioperative injuries, some were one-year outcomes, some were three-year outcomes. It's variable depending on -- there were various stages of reporting.

Q. Do you know whether or not those patients have been followed longer than that even though you haven't seen any reports about it?

A. I'm not aware of it. By the time that the product was available to be marketed, I'm not aware they had been followed for a long enough time to provide information so the surgeons and the patients could be well informed about what to expect.

Q. You have an opinion that Prolift and Prolift+M devices represent a significant departure from traditional surgical procedures. What traditional surgical procedures are you saying they are a significant departure from?

A. Primarily various types of native tissue repair. In some cases there had been reports on the use of mesh in reconstructive surgery transvaginally, but the early reports on mesh with transvaginal surgery did not involve the use of a trocar.

The mesh either would have been placed without a trocar, it may have been sutured in place --

those are for the synthetic meshes. For the -- for the synthetic permanent meshes.

For the absorbable meshes, those were almost always applied as an applique. So the traditional surgery -- excuse me -- was performed and then, for lack of a better term, a patch of a synthetic product was placed over that, and then the skin was closed. But none of those required the use of trocars to deploy the product.

Q. So the most significant departure that you're identified for me is the use of a trocar?

MS. THOMPSON: Object to form.

Q. (BY MR. WEBB) Or use of trocars?

MS. THOMPSON: Object to form.

A. The significant deviation from what we were accustomed to previously is deploying these arms into muscle, connective tissue, and through the skin, and as it turns out, really the only reasonable way to do that is to use a trocar.

So the real deviation was having the mesh arms through these tissue structures, and in order to put them in those places, it was necessary to use a trocar.

Q. (BY MR. WEBB) You say, "The vagina is a different environment from the abdominal wall.

Maintenance of vaginal compliance and distensibility is essential for bowel, bladder, and sexual function."

Had there been a transvaginal surgery to repair pelvic organ prolapse prior to the introduction of Prolift and Prolift+M devices?

A. Excuse me. Historically, the most common way to repair prolapse fell into two categories; one, obliterate the vaginal canal; or, one -- or, two, reconstruct the vaginal canal, ideally with a goal of having some degree of normal size of the vaginal canal and normal function of the bowel, bladder, and the vagina as a sexual organ.

So obliteration of the vaginal canal is an option in a very select subgroup of women, usually not very many of them, but for some. And that normally would only use suture materials, and that has been described as long ago as approximately 1850.

Reconstructing the vaginal canal to try to be more normal required a different level of anesthesia, and surgery -- general anesthesia only became safe in the mid to late 1800s. So reconstructive surgery is limited by the ability to have safe either regional or general anesthesia. So that began in the late 1800s.

And for all practical purposes, that was

what was used unless a doctor took the patient's own tissue, called fascia, to reinforce the repair. That would be called an autologous repair. So that happened in the early 1900s and later on during that century.

The concept of using mesh didn't really take hold until -- in gynecology, for example, until about the time a doctor in Wisconsin began -- he reported on using mesh for the anterior compartment without the use of trocars. Dr. Tom Julian did that, and he noticed that in his evaluation of these women, that anatomically they had improvement, but he also noticed that there was an issue about erosion or exposure of the vaginal mesh.

Q. You say that insertion of the mesh device containing arms and involving the blind passage of trocars presents specific risk and is inconsistent with sound pelvic reconstructive surgical principles. Is that correct?

A. Yes, sir.

Q. Is it -- if a surgeon chooses to use the Prolift or Prolift+M in using blind passage of trocars, is that below the standard of care if a surgeon chooses to do that?

MS. THOMPSON: Object to form.

A. When a surgeon chooses to use the blind

passage of trocars in deployment of a mesh arm, what happens in this specific case is the trocars are passed through tissue planes through which we normally never do surgery, and those tissue planes of connective tissue and muscle, primarily, have a vascular supply and a nerve supply which is variable.

All anatomy is variable from one individual to another, and when we pass these instruments without being able to see where they are going, we are using what we presume would be safe spots to place the product, place the trocar.

And the potential dilemma with that is that, in fact, for some people that may be a safe space to put something. Surgery is very operator dependent. And when I say "operator," I don't really mean surgeon. I'm talking about whoever's doing it. It is very -- the execution and the outcomes of surgery are dependent on the technical execution of an operation.

So let's use a trocar, for example. I don't have one here, but I have a pen. So when I'm using something like this to either sew with or to put into a tissue plane, I have the best control where I can begin the use of the instrument and see it. If I'm using a needle, for example, I have good control of where that needle goes in, but where the needle comes

out, the control isn't as predictable.

On a bigger scale, when you have instruments that are curved, what happens is when you think you are going into a particular plane, all the movement out here exaggerates the movement at the end of that instrument. So it's magnified.

So I think something is going in a particular spot, but depending on how I manage this part out here, that can deviate up or down or front or back, and I don't have that good of control over it. So that's one issue.

The second issue, the anatomy is variable. So even if I go where I think a place is safe, I can't see it, in fact. And you might ask, "Well, how is that different than, let's say, a suburethral sling, a midurethral sling, which uses a trocar," which is a reasonable question.

With midurethral slings, we're operating in spaces that surgeons, urologists, and gynecologists have operated on for hundreds of years. And if you need to see exactly what happened, you can make an incision in the abdomen or use a kind of instrument and see specifically where the trocar went or where the mesh went.

You can't do that with these products

that go through the muscles of the pelvis. Technically it isn't possible to do that, so that's a big departure.

MR. WEBB: Objection, nonresponsive.

Q. (BY MR. WEBB) I was asking: Is it below the standard of care for a surgeon to use Prolift or Prolift+M with a procedure that is recommended for the use of those products?

MS. THOMPSON: Object to form.

A. I don't think I said that in my general report. I don't believe I indicated that. So the answer is --

Q. (BY MR. WEBB) So what you said in your general report is insertion of a mesh device containing arms involving the blind passage of trocars present specific risk and is inconsistent with sound pelvic reconstructive surgical principals. And if it's inconsistent with sound pelvic reconstructive surgical principals, is it below the standard of care for a physician to do it?

A. I didn't say that. I said exactly what's there. And in my opinion, I would not use these products. Other people feel differently, that they can safely use them, and the risks are less than the benefit.

Q. Have you actually developed a medical device

yourself and presented it to a company or developed it yourself?

A. No, sir.

Q. Okay. Do you consider yourself an expert in biomaterials?

A. From a -- excuse me. I'm losing my voice.

From a clinical standpoint, I feel I'm an expert on evaluating people who have had biomaterials put in. From a laboratory standpoint, have I looked at these products under laboratory experimental conditions? I haven't done that.

Q. Do you have any experience in the manufacturing process of medical devices?

A. No, sir.

Q. Do you consider yourself an expert in toxicology?

A. No, sir.

Q. Do you consider yourself an expert in regulatory affairs or the FDA regulatory process considering medical devices?

A. I consider myself knowledgeable about what we are provided that meets the letter of the law, so I do consider myself knowledgeable about that.

Now, whether I agree that that's all the information we ought to have is a different issue, and I

don't agree with that, but I haven't submitted anything for approval by a government agency.

Q. Do you know the process that any medical device manufacturer goes through in order to get approval, whether it be by the 510(k), or whether it be by any other method to have a product approved?

A. I think I'm --

MS. THOMPSON: Object to form.

A. I think I'm familiar with the 510(k) in that the individual or the company who wants approval or clearance through the 510(k) process is required to provide certain documents, including is there a predicate device, and was a predicate device cleared before, and is the product that is being requested to receive clearance similar to the predicate device.

And then there's a governmental agency that makes a decision on that, yes or no. So I know that part of the mechanism.

Q. (BY MR. WEBB) Do you consider yourself an expert in that process?

MS. THOMPSON: Object to form, asked and answered.

A. I'm conversant with it. I don't know what it requires to be an expert about it.

Q. (BY MR. WEBB) Well, whether you're conversant

or not, do you consider yourself an expert in that?

MS. THOMPSON: Object to form, asked and answered.

A. Well, I don't know what you're asking me about being an expert. I'm knowledgeable enough to know that there is a process that has to take place and companies are -- companies actually make their own decisions about asking for 510(k) approval, if I'm not mistaken. And then once they get in the system, there are parameters that have to be provided, and then there is a government agency group that either asks for clarification on the information that's been requested, which has happened with Ethicon and J&J, and then the company has an opportunity to respond to that and can -- they come to a consensus on what is the adequate amount of information that's necessary before approval is given.

So I know those aspects of how --

Q. (BY MR. WEBB) Have you ever served on an FDA approval panel?

A. No, sir.

Q. Have you ever testified or been asked to give expert testimony in front of an FDA panel?

A. No, sir. Excuse me. No, sir.

Q. Do you know what the standard is by which the FDA will either approve or disapprove of any medical

device that's submitted for approval?

MS. THOMPSON: Object to form.

A. Well, in the case of a new product, they would require information about the technical -- let's use something in the pelvis, for example -- about the technical qualities, the description of what it is, what its intended purposes are, and if it -- if we have information about how this, in this case, product behaves in the laboratory, for example.

If they're -- if you're requesting based on similarity to a predicate product, then the person requesting clearance has to say that their newer product is substantially equivalent from the predicate device that was previously approved and provide the information to document that.

Q. (BY MR. WEBB) You talked a little bit about the process. You didn't tell me what the standard is that the FDA looks at.

MS. THOMPSON: Object to form.

A. I don't know that I can articulate the standard.

Q. (BY MR. WEBB) Have you ever studied the properties of polypropylene mesh in the laboratory?

A. No, sir.

Q. Have you ever looked at any mesh, Prolift or

Prolift+M, under a microscope, even?

A. No, sir.

Q. Ever done any degradation testing on polypropylene mesh?

A. Excuse me. No, sir.

Q. Any elasticity studies?

A. In that standpoint, only in the clinical aspects of palpating products that have been placed in someone in making my own clinical assessment of whether or not those tissues are tightly stretched out or not. So from a clinical standpoint, I've done that.

Q. Have you ever quantified that, or is that a subjective test according to your --

A. I'm not aware there's a -- with the exception of looking at ultrasound, which, actually, I don't think measures elasticity anyway, there is not an objective way -- all the other reports I'm familiar with are a clinical assessment.

Q. Have you ever done any shrinkage studies to see -- personally done any shrinkage studies to see if there's any shrinkage of polypropylene mesh?

A. Not in the laboratory. Again, I would rely on my clinical observations. And one of the ways that I have observed clinically about shrinkage is in the case of midurethral slings where I, in fact, have placed the

sling myself and I may later operate on the woman because she has a reason for reoperation. Excuse me.

In identifying the sling product, I can, in that circumstance, make the observation that that sling is more tightly applied than it was when I did the surgery previously, if that surgery was a week ago or years ago, which could have been the case, that it doesn't have the same freedom of lack of tension that it had when it was originally placed.

And then the presumption would be that that is -- that the mesh is -- the dimensions are getting smaller through the wound healing, scar formation, or some intrinsic product -- some intrinsic characteristic of the product itself.

Q. Do you --

A. So I have seen that in my own patients.

Q. Using a -- what is generally considered to be a cure rate of -- for surgeons in your practice, what would you say the cure rate is, roughly, for the patients that you have used polypropylene mesh in for the years that you've been practicing and using that mesh?

MS. THOMPSON: Object to form.

A. For the treat -- excuse me. For the treatment of urinary incontinence?

Q. (BY MR. WEBB) Yes, sir.

A. Yes, sir. My observation is from the time I began my work in 1975 where I am right now, until about 2001 or '2, so that would have been 25 years, more or less, I did surgery for urinary incontinence using native tissue only.

And the clinical outcomes of the patients that I used native tissue for compared to the women in whom I used the midurethral sling following 2000 and 2001 -- that became my operation I did more frequently -- I would say the absence of symptoms of incontinence were similar with both of those, so -- in everybody who's tested it.

So I haven't reported on that. But the people who do report on it, the conclusions are that the outcomes of cure of incontinence are very similar with the synthetic midurethral sling as with the previous operations which didn't require sling material. So I think there is a consensus about that.

Q. And what is the percentage that you would say?

A. It's -- it's time related. So the earlier after the procedure the patient is evaluated, the more likely they're to be cured. And the cure rate is a function of time, so the longer you follow someone, the cure rate has a certain deterioration every year.

But in the first year or so, the patients are counseled that approximately 80 percent are going to be satisfied with bladder control, coughing, laughing, straining, and sneezing.

Depending on how stringent the requirements are for objective proof, the cure rate isn't that high. But practically speaking, most doctors are going to use the patient satisfaction issue, and about 80 or 85 percent are going satisfied.

Q. Have you ever followed a patient who had a Prolift product in order to quantify any shrinkage or degradation or anything that you would follow over a long period of time?

A. I think there are several groups of patients. I have seen some patients, and I believe they've had Prolift, but if you ask me to prove that, I don't -- can't prove it today. But I have seen patients who had, for example, posterior Prolift, who have come to me for concerns about pain in the vaginal canal or pain with bowel function because the mesh itself isn't distensible, and when their bowel works, the mesh can create a delay in bowel emptying.

So in some of those women, I've examined them and said, yes, I think this product has more tension on it than was ever intended, but I didn't put

it in, and I suspect it's tighter than it was before. And the patient may choose not to have anything done, and I may see her back for evaluation later, and she still may not have symptoms for her that warrant another operation. So I've seen people like that.

I've seen some people who have had anterior Prolift, and they don't have a complaint about anything. They want to be seen, frankly, because they're curious, is there something the matter with me because I've had this product. And I may examine them, and I may say, "No. I think presently you're okay," and I wouldn't do anything, and I would -- just be followed periodically.

So there's a subset of people who, for all practical purposes, when I've seen them are clinically doing well, and there's no reason to recommend doing anything.

Q. Have you ever personally observed any degradation of any Prolift product?

A. Well, that's a microscopic diagnosis, and the answer is no.

Q. Has anybody ever reported to you when you sent something to a pathologist of any degradation of any Prolift product?

A. You know, on my specific patients, our

pathologists haven't. Now, it's possible that some of the patients that I've operated on have had specimens sent elsewhere for evaluation.

Because periodically what will happen, I'll operate on someone to revise or explant graft material, and the request from the patient and her legal counsel is to forward that tissue on to someone else, in which case I don't think I ever received a report on that. We follow their request and submit it to someone, but I'm not in the loop where I would get a report back to observe that.

Q. Are you aware of any studies in the medical literature in the 2000 to 2005 timeframe that found good results with the use of transvaginal mesh kits?

A. I'll have to look specifically about -- about the year. Just a moment.

The -- did you ask me mesh kit? Is that what you asked me, or mesh?

Q. Mesh kits.

A. Mesh kit. I don't remember what -- excuse me -- in that timeframe, and when I look -- excuse me.

When I look in the bibliography of an article by a Dr. Jacquetin, who developed Prolift -- and this is a report in 2009 on the total vaginal mesh technique. When I look at his bibliography, I don't see

any reference to something published using a mesh kit during that time period from 2000 to 2005. He referenced Dr. Julian, whom I spoke about earlier, and that article was -- was reported in 1996, and it was a mesh applique.

So I don't know about reports on the mesh kit before 2005.

Q. How did you reach the conclusion that Ethicon did not provide doctors and patients with complete and accurate information regarding the complications associated with Prolift and Prolift+M devices and their management?

A. Because some of the information we only learn as time goes by about long-term outcomes. That's a variety of things that we do. And I'll use abdominal sacrocolpopexy, which has been an operation around since 1950 or so.

Some of the concerns about abdominal sacrocolpopexy in terms of mesh erosion or exposure only are evident years after the original repair or some of the other complications regarding adhesion and bowel perforation. So we know from another pelvic reconstructive procedure that the true story unfolds over a time period.

And the reason I don't think people were

provided adequate information is, one, there wasn't enough time to go by to find out have we seen the bulk of these issues or what is the natural history of these women? That's one thing.

And then the second thing is it isn't clear that that objective of some of these early studies was really to look at, for example, quality of life or effects on pain or sexual function. The early studies were primarily on anatomical outcomes and the perioperative morbidity. And that's why I think it would be hard for me to counsel someone based on the information that was available in 2004 or '5 or '6 or '7. The information just wasn't available.

Q. Well, it's not that Ethicon held it back. It's just that it wasn't available. Is that what you're saying?

A. Well --

MS. THOMPSON: Object to form.

A. Well, certain information clearly wasn't available, and then whether or not there was knowledge -- and there was knowledge about some of the things regarding exposure rate and pain, for example. It's hard -- you can say that someone has pain, for example, and that can be disclosed in the information for use document, but it doesn't necessarily go into

detail about the severity of the pain, how frequently it occurs, and how long it occurs.

So I could say that, well, I knew there could be pain associated with it, and maybe the patient knew there was pain, but in my opinion, that isn't the full extent of what someone would want to know about the outcome of surgery. I don't think we had all the information.

Q. You don't think Ethicon had all that information?

A. I don't think that --

MS. THOMPSON: Object to form.

A. I don't think they had all of it, because not all of the trials were designed to collect that information. Plus not enough time had gone by.

Q. (BY MR. WEBB) You say Ethicon failed to disclose the lack of benefit of pelvic organ prolapse surgery using Prolift and Prolift+M devices to physicians and patients.

What do you base that opinion on?

A. Well -- excuse me. Again, it's a question of time and how you report the information.

I'll give you an example. This article by Dr. Jacquetin published in 2010 was called, "Total transvaginal mesh technique for treatment of pelvic

organ prolapse, a three-year prospective follow-up study."

Dr. Jacquetin and his colleagues were and are the most knowledgeable about the technical aspects of the procedure, and I would presume they are very knowledgeable about patient selection.

So this is the group who conceived of the idea, who have the most skill associated with it, and at three years after surgery, one out of five women had an anatomical failure rate, and one out of seven had mesh exposure.

So when I say "benefit," the benefit is 80 percent of people got better, 20 percent had an anatomical failure. That's not appreciably different than someone who had native tissue surgery.

I reported on my own experience previously, ten years before that, using native tissue, and there's no appreciable benefit to -- in my patients to using the product when you look at anatomical outcomes, for example. And I didn't have one out of seven patients with mesh exposure.

So that's what I mean when I say I don't think patients were fully informed of the benefit. So you might -- if you ask me specific benefits, besides anatomy, then I'll try to respond to that. But in the

absence of that, these trials, these reports are based primarily on anatomy.

And that was the concept to begin with. Surgery doesn't have as good an anatomic outcome as it should; i.e., we need to do something different to try to improve it.

Q. Your opinion that removal of mesh is always a complex surgery, is it your personal experience that every removal surgery is complex?

A. It can be. I think you have to be aware of that. Now, again, I'll say surgery is like every job. Sometimes you start the job, and technically it's easier than what you anticipate, but sometimes the converse of that is true. You think this will be not particularly difficult, and it actually is.

So you have to be prepared that it can be difficult, and, in fact, some of the explant procedures are technically very challenging. Not all of them are.

Q. What's your basis for saying that Ethicon lacks scientific rigor in testing and reporting of its pelvic floor products?

A. I think I've alluded to it before. Under a circumstance which would have been better is there would have been, sequentially, the concept of what ought to be done, and after the concept, then is it practical to do

what conceptually you have in mind to do.

And if what you want to do has a proposed benefit, you have to be very clear about what that benefit is as well as articulating what the possible risk could be. So if you do this, whatever it is, have in mind what -- the possible adverse events that could occur, and we need to monitor those.

And then in order to say, "I'll use this group of Dr. Jacquetin" -- and I'm using him because he's knowledgeable about this. So if Dr. Jacquetin has worked on a way to have better outcomes from surgery, the real way to know that is he would have to compare this innovation to what he was previously doing in a fashion that is ideally not biased, and then in a period of time he could look at that and say they're equal or they aren't equal, and they're not equal for whatever the reasons are. I don't see that as having transpired.

I see it as having recruited a number of women to undergo a procedure and then make longitudinal observations about them as opposed to comparing it with something done, which under ideal circumstances is how it would work.

Q. So this is another one of your opinions that criticizes the lack of a clinical study with the parameters that you would expect to have in a clinical

study. And because of the critique that you have, you feel that Ethicon failed to do proper studies to show the safety and the effect -- the efficiency or the efficacy of this product?

A. Yes, sir.

Q. Have you personally ever put together a scientific clinical study that has been used for any medical device or any drug?

A. The one -- excuse me. We have done two relating to the Gynecare TVT. And one of them was in an effort to minimize the likelihood of getting a bladder infection following the procedure. We had a randomized trial where women who were going to undergo a TVT were either given an antibiotic for a defined time period or not.

And then we had another with a retropubic sling, looking at injecting the retropubic space with what's called hydrodissection -- that's part of the IFU -- with hydrodissection with the use of saline versus the use of a local anesthetic agent to see if that affected the amount of pain medication that a patient would need in the recovery period.

So we didn't design a product. We did look at two randomized trials where patients were approved -- the Institutional Review Board approved the

protocol, and patients were informed they were in a trial to try to learn the best way to effect the procedure, to minimize pain, and minimize urinary leak -- urinary infections.

Q. So they were approved by your Institutional Review Board?

A. Yes, sir.

Q. Were they approved by the FDA?

A. No, sir.

MS. THOMPSON: Object to form.

A. No, sir.

Q. (BY MR. WEBB) Were they ever submitted to the FDA?

A. No, sir. It wasn't required.

Q. Did you ever -- do you know whether or not any of the testing done by any of the doctors using Prolift or Prolift+M was approved by Institutional Review Boards?

A. Yes, sir, I do. In France, I believe that some of those were approved. And some of those that were multicenter. I'm not sure that every center in every country required that, but, yes, I know for a fact some of them were.

Q. Do you know whether or not they were approved by the regulatory bodies in the individual countries?

MS. THOMPSON: Object to form.

A. No, sir, I don't know that.

Q. (BY MR. WEBB) The two randomized studies that you -- or trials that you worked on, did you publish the results of those trials?

A. Yes, sir.

Q. And were they submitted to a scientific journal or a medical literature journal?

A. Yes, sir. They were presented in a scientific meeting, and the authors were fellows of ours, and the one on antibiotics was a multicenter one with a group from the University of Missouri, as well as from us, and the one on the local anesthetic was in our organization only.

Q. Was it a poster presentation? Was it an abstract? Was it actually an article submitted to peer-reviewed literature and published?

A. I know for a fact one of them was an oral presentation. The one that had the primary author from the University of Missouri, I don't know if that was oral, but it's been published. And the one that Dr. Jessica Bracken did, who works in our organization, presented it, and to the best of my knowledge it's published, but I can confirm that if you give me -- at least -- it may not be in my CV, but she's the primary

author for it.

Q. You have some criticism in Opinion No. 13 that Ethicon did not exercise due diligence in the design and development of Prolift and Prolift+M devices.

Have you ever designed or developed any medical device yourself?

A. Excuse me. No, sir.

Q. Did you ask for and receive all the Ethicon documents that referred to the design and development of the Prolift and Prolift+M devices?

A. I didn't ask for them. I doubt seriously I received all of them.

Q. In the half banker box of documents that we have that are sitting here on the table that you were provided by plaintiffs' counsel, did you see any documents in there related to the design and development of the Prolift and Prolift+M devices?

MS. THOMPSON: Object to form.

A. No, sir.

Q. (BY MR. WEBB) What's the basis, then, of your opinion that Ethicon did not exercise due diligence in the design and development of the Prolift and Prolift+M devices?

A. The clinical outcomes. The patients -- patients have been harmed.

Q. You understand that the FDA has required as its standard that a medical device must be safe and efficient -- it needs to be effective -- safe and effectively for its intended use. Do you understand that?

MS. THOMPSON: Object to form.

A. I know that -- excuse me. I know there are different levels of clearance for approval for products, and some require a lesser amount of documentation than others.

And initially, the 510(k) for these products required a lower level of substantiating information than is currently being requested by the FDA.

Q. (BY MR. WEBB) In order for a medical device to remain on the market, it must be safe and effective for its intended use. Correct?

MS. THOMPSON: Object to form.

A. I don't know the answer to that.

Q. (BY MR. WEBB) Would you agree that if the FDA feels that a medical device is neither safe nor effective -- not safe or not effective, that it should be removed from the market?

MS. THOMPSON: Object to form.

A. I would presume that would be the case.

Q. (BY MR. WEBB) Do you know if the FDA has ever requested that Prolift or Prolift+M be removed from the market because they were not safe or effective for their intended use?

MS. THOMPSON: Object to form.

A. What I know is that the FDA hasn't removed -- not only their products, the other products -- but the products -- most of the products are no longer sold. And the companies have made that decision themselves. So the FDA wasn't obliged to make that decision.

Q. (BY MR. WEBB) Well, the question I asked you: Has the FDA ever said that the Prolift or Prolift+M products are neither safe or effective and must be removed from the market?

MS. THOMPSON: Object to form.

A. What the FDA has said is that the companies will continue to make the products. There's a different level of documentation that has to be submitted, including further trials of safety and efficacy, and for some product for some companies, they're attempting to do that.

For other products, including these products, that hasn't been done, and the products aren't available. But the FDA didn't take them off the market. The company chose to quit selling them.

Q. (BY MR. WEBB) You say that the -- Ethicon did not heed the warnings from the hernia and gynecologic literature regarding the use of polypropylene mesh. What are you talking about there?

A. Well, in hernia repair, which is what my report is generally about, there have been warnings about using a synthetic product in an infected wound, for example. So let's use the case of abdominal or inguinal hernia repair, general surgical principles, which we referred to earlier, would say that you wouldn't put a synthetic product in an infected wound.

The vagina -- the vaginal canal is never sterile. It's what's referred to in medical terms as a clean contaminated field. So a hernia surgery isn't in a sterile field. A vaginal surgery is in a clean contaminated field.

There was evidence in other literature that -- in the general surgery literature and the pathologic literature that mesh, in fact, does contract in animal models as well as in humans when used for hernia surgery, and there are people who had pain complaints.

So when -- this specific reference that you gave that I have in my general report is, in my opinion, those issues weren't adequately addressed

before the company marketed a product -- synthetic polypropylene mesh to put in a clean contaminated field, which is what the vaginal canal is.

In some of the articles in the folder which I have given you -- and I'd have to look them up -- that issue is actually highlighted, the vaginal canal is not the abdominal cavity or abdominal wall, either one.

Q. Ethicon inappropriately marketed the Prolift and Prolift+M products to all physicians and did not properly train these physicians in the unique aspects of patient selection and patient counseling of long-term sequelae of trocar-based mesh kits.

Does a company like Ethicon have the right to tell a physician they cannot use a medical device that's been approved by the FDA?

MS. THOMPSON: Object to form.

A. My -- my reasoning for that comment is in the Ethicon study group, the transvaginal mesh group, highly educated, highly skilled, highly experienced with a level of complications I've already referred to, 20 percent failure rate at three years, one out of seven with mesh exposure, and these were people who had extensive experience in monitoring.

When the product was available for sale,

physicians could request training if they wanted it, and Ethicon may provide it.

Is it reasonable based on the knowledge that was obtained from the early studies to say that someone should have training before a product is used? In my opinion, that's a reasonable thing to do, because the truth is not everyone is equally capable of doing these procedures, and, in general, when people who are advocates of using this particular mesh product comment on complications, one of the variables that's pointed out is the surgeon's technical skills are involved in the complication.

MR. WEBB: Objection, nonresponsive.

Q. (BY MR. WEBB) The question I asked you: Does Ethicon have the right or ability to tell a physician they cannot use a product that's been approved by the FDA?

MS. THOMPSON: Object to form.

A. I don't know that they would. I'm sure they could.

Q. (BY MR. WEBB) So your testimony is that a company could tell a physician that they cannot use an approved medical device, even if they refuse training, that they're using it inappropriately, but a company like Ethicon could refuse to sell to that physician?

MS. THOMPSON: Asked and answered.

A. Well, you're asking, I think, a hypothetical situation, that could the company do it or is it legal. I mean, I think those are two separate issues. Could the company do it, and then when the physician or physicians say, then, "You're restraining my practice of medicine," and then it becomes a legal issue about that -- I suspect that's probably what would happen.

I don't -- when you ask me can Ethicon do that, I don't know the legal requirements for that.

Q. (BY MR. WEBB) You expressed an opinion that said that Ethicon inappropriately marketed the Prolift and Prolift+M products to all physicians.

Does Ethicon have the right to deny the use of their products by a properly licensed physician?

MS. THOMPSON: Object to form, asked and answered.

A. I think there's -- that's not a binary question. There is nothing that I know of that says there's a minimum skill set required to use this product. That would be a reasonable thing to have done, to say, "In order to use this properly, you should have this amount of knowledge to use the product I am making and use it successfully."

That's an opinion. So you asked my

opinion, and that's mine.

Q. (BY MR. WEBB) Okay. And so what's the basis of that opinion?

A. Patient safety.

Q. If a physician refuses to be trained in the unique aspects of patient selection, patient counseling, is there anything that Ethicon can do if they refuse to be trained in the use of the products?

MS. THOMPSON: Object to form.

A. I don't know the -- excuse me. I don't know legally if Ethicon could do anything about that or not. Ethicon, by the way, doesn't sell to individuals, I don't believe. I think they sell to hospitals, but I may be wrong about that.

In our case, the hospital buys the product, because it's a hospital-based procedure. In other areas, it's possible that individual physicians can purchase it, but I don't know that.

Q. (BY MR. WEBB) Well, how in the world is Ethicon even supposed to know the level of expertise or competence of physicians if they're selling it to the hospital, whether or not those hospitals are allowing physicians who are not competent to use the product?

MS. THOMPSON: Object to form.

A. I don't know the answer to that.

Q. (BY MR. WEBB) Is it your opinion that Ethicon did not have a system in place to monitor their product or evaluate physician feedback on the products?

A. If they had one, it wasn't obvious to the physicians who were using the products.

Q. Do you know whether or not the FDA requires that there be adverse event monitoring on all approved medical devices?

MS. THOMPSON: Object to form.

A. There is the MAUDE database which people can use. I don't know that the FDA can require a physician to report adverse effects.

MR. WEBB: Nonresponsive. Objection; nonresponsive.

THE WITNESS: I'm sorry. I didn't understand your question.

Q. (BY MR. WEBB) Does the FDA require that there be an adverse event database maintained for any approved medical device?

MS. THOMPSON: Object to form.

A. I believe that depends on the level at which the device -- in terms of the potential injury, you know, Level 1, 2, or 3.

So the greater the potential for risk, then there may be a requirement for that, but I don't

know that for sure.

Q. (BY MR. WEBB) In any of the Ethicon devices that you use in your practice, did you receive training by any sales personnel?

A. No, sir. I saw the products demoed at meetings, but there wasn't a non-physician representative teaching me how to use the product, if that's your question.

Q. They were demonstrated at medical meetings by other physicians who were using the product?

MS. THOMPSON: Object to form.

A. That's one way. And then at the medical meetings, at the scientific exhibits and the commercial exhibits, various companies, regardless of what they're selling, will have part of their sales force present to inform people about what they're selling, and they may or may not have a physician available to talk about the physician aspects of it.

So early on in the introduction of the retropubic slings, for example, it was common at meetings to have a physician or more than one physician present discussing the use of a product, and it would be common to have a representative of the company there to answer questions or to ask if you needed more information, publications and whatnot.

Q. (BY MR. WEBB) There's also sales literature, and there's also, sometimes, videos or CDs?

A. Yes, sir, there frequently are.

Q. In your expert report, there's a section about examples of Ethicon documents supporting these opinions. Are all these Ethicon documents that you have placed in the report, are they documents that were provided to you by plaintiffs' counsel and came out of the banker box that we have here?

A. Yes. Excuse me. Yes, sir.

Q. Okay. And as you read through those documents, did you request other documents because you saw something referenced and you wanted to see if there was any follow-up? For example, if there was an email chain, did you ask what happened after this issue was raised?

A. To the best of my knowledge -- excuse me -- I did not do that.

Q. In one of the Ethicon documents they report that Professor Jacquetin is the inventor of the pelvic floor repair technique Gynecare will be marketing this year.

Do you know whether Ethicon worked with Dr. Jacquetin or whether it was something he came up with on his own and then approached the company?

MS. THOMPSON: Object to form.

A. I don't know that for a fact. I know him, and I was present when he did one of these mesh kit procedures in Italy before the product was commercially available because he and I were doing live surgery at a surgical course outside of Milan, Italy.

And I know that he worked with his group on the concept, but I don't -- to the best of my knowledge, Ethicon or J&J did not approach him to develop a concept, if that's the question. I believe the idea was his and his group.

Q. (BY MR. WEBB) Some of the documents you reviewed are actually presentations that were made either in-house or externally by Ethicon. Is that correct?

A. Yes, sir.

Q. And you've identified some of the problems that they were discussing both internally and what they were discussing in -- outside the company in some of these documents that you've included in your report. Correct?

A. Yes. Excuse me. Yes, sir.

Q. Will you agree with the concept that on any medical device, the longer it's in use, the more we understand both the risks and benefits of any medical

device?

MS. THOMPSON: Object to form.

A. I would say generally that's true.

Q. (BY MR. WEBB) Have you talked -- or read any depositions in which the documents that you have included, the Ethicon documents you included in your expert report are discussed or explained?

A. I don't believe I have. Excuse me. I don't think so.

Q. On some of these documents, did you just take portions of the document to include it in your expert report?

A. I'm sorry. I don't -- can you give me an example of that?

Q. For example, if you go to Page 44 of your report.

A. I gave you my only copy of the report. I'm sorry.

Q. Okay. Did you take out paragraphs or excerpts sometimes in order to make the point that you wanted to make but didn't include the entire document?

A. I'm sure that's possible that I did.

Q. Were you aware that in some of your past general reports, some of your opinions have been excluded by the federal court for various reasons?

A. I -- excuse me. I haven't seen the detailed comments on that, but in general, yes, sir, I understand that's true.

Q. Would you agree with the statement that experience as a surgeon alone does not translate into experience with or knowledge of the appropriate testing a medical device manufacturer should undertake when preparing a device for the market?

A. Is that something I said in my report?

Q. No. I'm asking whether you agree with the concept.

A. I'm sorry. Would you repeat that again?

Q. Sure. Experience as a surgeon alone does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a device for the market?

A. It may not encompass everything, but experience of the surgeon would certainly incorporate some of the things that would be appropriate to look for.

Q. Do you feel that you have additional experience with product testing or clinical trials that sets you aside from an average pelvic surgeon related to the transvaginal mesh?

A. I wouldn't normally say this about myself. I

know a lot about pelvic surgery because that's what I do.

So I know a lot about it, and other people recognize that because I see people and offer them options for non-surgical, medical, or surgical therapy, and I follow them up. And I've seen people who have been treated with various other surgical techniques that I may not personally use, and not all of them are patients who have a problem.

But the truth is I do see women who have had problems, and I feel, as an experienced, knowledgeable person, that I am more knowledgeable than the average person doing pelvic surgery. That's what you asked me. I think I am.

Q. Do you consider yourself to be knowledgeable and trained and have experience with the design of clinical trials?

A. Yes, sir, because I told you that we did several.

Q. Have you ever done one on a testing of a medical device, not the -- the two that you talked to me about were actually not testing a medical device but testing the protocols about using a medical device in certain circumstances?

A. That's correct.

MS. THOMPSON: Object to form.

A. You're accurate about that. And then I referred to one other, which doesn't have any name on it, which was the animal model looking at Pelvicol. But have I done a study looking at a specific pelvic -- or a specific device in surgery from a clinical standpoint in humans, and the answer is no.

Q. (BY MR. WEBB) Do you consider yourself an expert in the regulations or standards that govern IFUs?

A. I'm not in a position to be involved in the regulations. I'm in a position as a user to know what would be reasonable for me to know about. So in that sense, I do feel I'm an expert on the receiver end. I'm not an expert on the development end.

Q. Have you ever advised a company on how to design or word an IFU?

A. No.

Q. Are you familiar with the industry process governing IFUs?

A. I do not know the process.

Q. Have you ever performed a literature search relating to IFUs?

A. You know, actually, I have read about IFUs. That was several years ago, and I don't have it in my report, but the truth is I have looked at that and

looked at the fact that there are certain requirements, but -- so I've read about it. I don't -- I haven't participated in developing an IFU.

When I read the 510(k) application for these products, part of the exchange with the agency and the company was what to include in the IFU, and part of the correspondence is -- which you have as documents from Ethicon -- discussed whether or not the IFU ought to be modified to include other information.

MR. WEBB: That's all I have.

MS. THOMPSON: I'll have a few questions, but I'll just reserve them until the end of both depositions, if we can agree that they apply to both.

MR. WEBB: That's fine with me.

MS. THOMPSON: All righty.

THE VIDEOGRAPHER: This concludes the deposition of Dr. Shull. Going off the record, the time is 12:00.

(Recess from 12:00 p.m. to 1:01 p.m.)

THE VIDEOGRAPHER: Back on the record. This marks the beginning of Disc No. 3. The time is 1:01.

Q. (BY MR. WEBB) Dr. Shull, we took a break, and this morning we were talking about Prolift and Prolift+M, and you -- we went through your expert

report, your general report about those products. Is that correct?

A. Yes. Yes, sir.

Q. Okay. And you have a separate expert report that you have prepared for the Prosima product. Is that correct?

A. Yes.

Q. And as we walk through, it appears, when I compare your expert report for the Prolift and Prolift+M to the Prosima expert report, there's a lot of it that's very similar in some general details. Would that be a fair statement?

A. Yes, sir.

Q. All right. And what I will do is I may just ask you questions and say, "Would your answers be the same about Prosima on these areas that are identical to the Prolift and Prolift+M," and then you can either agree with me or tell me how they differ. Is that a fair way to approach it?

A. That's fine.

Q. All right. You have prepared -- and by the way, is there any substantial difference in your mind between the Prolift and the Prolift+M?

MS. THOMPSON: Object to form.

A. The Prolift -- the original product was

entirely non-absorbable. The Prolift+M was different in that a portion of the graft material is absorbable. That's the primary difference.

To the best of my knowledge, the delivery system itself was basically the same.

Q. (BY MR. WEBB) And we had some discussion this morning when you were talking about absorbable material when we were walking through the Prolift and Prolift+M. Is that correct?

A. Yes.

(Exhibit No. 5 marked)

Q. (BY MR. WEBB) In your mind, is there any substantial advantages or disadvantages to either a Prolift or the Prolift+M?

A. I don't know that any advantages were documented. The presumption was that by making a portion of the Prolift absorbable by replacing the nonabsorbable portion with Monocryl, that there would be less mesh product left in the patient, and a variety of problems could be minimized.

As I understand it, that was the rationale for developing the Prolift+M. I don't know that that's ever been proven to be the case.

Q. Have you seen any literature that would prove it one way or the other?

A. No, sir.

Q. I'm going to show you what we've marked as Exhibit No. 5, which is basically your expert report on Prosima. Do you have -- that's actually -- just giving you back your Prolift one there.

A. I beg your pardon?

Q. And you have with you a copy of -- and what I've done is just marked a copy I have of your expert report.

A. This is the Prosima -- you have my updated curriculum vitae, and here is the time sheet for working on the Prosima report.

Q. Okay. The -- so Exhibit No. 5 is the Rule 26 expert report of Bob Shull regarding Prosima. Is that correct, sir?

A. Yes, sir.

Q. Okay. And what you've given me is a time sheet related to the time spent in reviewing documents, researching, and preparing your report on Prosima. Would that be a fair statement?

A. Yes. Yes, sir.

(Exhibit No. 6 marked)

Q. (BY MR. WEBB) The top page of Exhibit No. 6 looks like to be a check stub that was sent to you for $7,637.50, which matches an invoice dated February 7th,

2016 that was sent to -- once again, you just have it listed as Margaret on the invoice?

A. Yes. I sent it to her to distribute to the appropriate individuals because she had the contact addresses and whatnot.

Q. And that's Margaret Thompson. Right?

A. Yes, sir.

Q. Okay. You list review documents and literature for 180 minutes. Finish review -- discussed with Margaret and Breanne draft report, 365 minutes. Revise and -- review and revise draft, 100. And final report -- or phone call with Breanne and final report, 60, for a total of 705 minutes, or 11 hours and 45 minutes at $650 an hour, which was $7,637.50.

Is that correct, sir?

A. Yes, sir.

Q. Okay. Let me ask you generally: Were you provided separate documents for the Prosima -- separate Ethicon documents for the Prosima product?

A. Yes, sir. They're in this binder that I have. These -- frankly, I can't remember why I have them out separately, but I do. They relate to the Prosima, and I don't believe I took them out of here -- and they may be duplicated in here, but I have everything that I used in this binder and in the -- or in the back of the front

page.

MR. WEBB: Margaret, does the thumb drive that you gave me earlier, does it cover this also?

MS. THOMPSON: It has both Prolift and Prosima documents, yeah.

MR. WEBB: All right.

Q. (BY MR. WEBB) In the Prosima binder that you gave me, there is a series of articles at the front, and I'll just read them into the record. There's only five, I think.

The first one is "Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device," published in the "BJOG: An Interventional Journal of Obstetrics & Gynecology," and it's dated 2008 -- accepted October 23rd, 2007.

Then there's the -- an article, urogynecology, "One year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device," the "American Journal of Obstetrics and Gynecology," December 2010.

"Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device." It looks to be the "International Urogynecological Journal," published online December 6th, 2011.

"Anatomical study of prolapse surgery with nonanchored mesh and a vaginal support device," the "American Journal of Obstetrics and Gynecology," 2010.

"Case report: Internal pudendal artery injury during prolapse surgery using nonanchored mesh," the "Journal of Minimally Invasive Gynecology," and accepted for publication June 23rd, 2011.

Are these the articles that specifically relate to Prosima that you -- Prosima that you relied upon in preparing your report, Dr. Shull?

A. Yes, sir.

Q. Why did you understand that it was potentially desirable to have a vaginal support device when you're doing a surgical procedure for pelvic organ prolapse?

A. The way I understand the evolution of this type of surgical procedure is that the authors hoped to avoid the use of trocar placement for the arms or the straps of the Gynemesh.

They understood that if the arms weren't fixed either by trocars penetrating tissue spaces or by stitching them in place, that there would need to be an alternate way to keep the mesh approximated to the anatomic spots where they were placed at the time of the surgery.

I don't recall if the authors had tried

using glue of some sort to hold the straps in place. It's possible they did, but I don't remember that.

The mechanism they chose to use was to place the mesh straps into defined spaces, and then for a time period in the recovery, use an object -- excuse me -- which could fill the vaginal canal and minimize the likelihood that the mesh arms or the mesh central portion would either move or be displaced, and that while the vaginal support device was in place, wound healing would begin and perhaps keep the tissue in its desired location.

Q. When was this product placed on the market?

A. I believe the product was actually sold beginning in 2009.

Q. And when was it withdrawn from the market?

A. I believe that it was no longer available for sale sometime in 2012.

Q. What is your understanding about the success rate of this product?

MS. THOMPSON: Object to form.

A. In my review of the literature, the primary physicians who developed the concept of vaginal support device and the nonanchored mesh were Dr. Marcus Carey and Dr. Mark Slack.

And Dr. Carey published an article -- or

he began to recruit patients into a study that compared patients who had the nonanchored mesh to patients who had traditional surgery so he could have a baseline to determine what kind of success is obtained with standard surgery. Then he hoped to be able to improve on the anatomical outcomes using the vaginal support device.

And as he developed this product, he did a study, in fact -- and that's involved in the articles I have -- as the first step toward justification for advancing on to a study using the device which ultimately became Prosima.

Q. (BY MR. WEBB) And is the study you're talking about the one that's entitled "Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device"?

A. This is not the first study. Actually, the first group of patients recruited -- I believe that article was reported in 2009, actually. It may be the first one in the binder which I gave you there.

This is a subsequent group of patients that -- for whom Dr. Carey, who is from the United Kingdom, was the primary author. Dr. Slack was the primary author on the patients who were recruited initially for the comparison of --

Q. Does that look like it's the same article to

you?

A. Let me just look at the next one.

Yes, sir, it is the same one. I'm sorry. I'm sorry. It is the same one. But there's another one which was published a little later. I just have to find it. Maybe I have it in here.

Well, actually, there's another one I recall, which I referenced in my report, but I can't find it right here, as a matter of fact. May I see my general report just a moment?

Okay. I do have the other article. It's the one-year clinical outcomes. I beg your pardon. I have that.

Ask me the question again, would you, please? I started looking, and I forgot exactly what you asked me.

Q. I think the question was whether or not the article that I handed you was the same as --

A. Yes, sir.

Q. -- the article that's the first article in your binder?

A. Yes, sir, it is. And I think what I must have done, I must have copied these articles and just taken them out separately, because this binder has other information, and I wanted to be able to just work with

these. I thought that they may be different, but they're not.

Q. And were these articles in the information in the binder that was provided to you by plaintiffs' counsel?

A. Yes, they were.

Q. The five articles that I read the names into the record, were those provided by plaintiffs' counsel, or was that something you found in your own independent research?

A. They were provided by counsel.

Q. Okay. It appears there's also some internal Ethicon documents?

A. Yes, sir, there are.

Q. And some product literature related to Prosima?

A. Yes, that's correct.

Q. Does it appear that Dr. Carey's research was an attempt to address some of the issues that you had reported or that you had opined about this morning regarding the use of trocars when using the Prolift and the Prolift+M products?

A. Yes, sir. Excuse me. And the other thing he did is before doing that, he reported -- and that's the article that is actually in the British Journal of

Obstetrics & Gynecology in 2009. Dr. Carey took a group of patients that he himself recruited and operated on doing mesh with standard surgery so he would have a baseline to know in his own experience what the anatomical outcomes were using mesh alone or using no mesh.

He did that first, and then he worked on the vaginal support device in an effort, as you pointed out, to see if not using trocars would minimize or eliminate some of the initial complications with using a mesh product.

Q. Do you have a complaint -- looking through your report, it's not clear to me. Do you have a complaint about the vaginal support device itself, or are your complaints related to the use of mesh in the type of surgery that the Prosima is used in separate and apart from the vaginal support device?

A. Well, the vaginal support device had as its predicate a device called Silimed, which was cleared to use in women having radiation therapy on the pelvis or having pelvic -- creation of a new vagina. The Silimed was used to try to maintain the caliber of the vaginal canal.

In this particular use of it, there's a different indication for the use because these women

were having reconstructive surgery using a synthetic product. The Silimed hadn't been used for that previously. The thing that it did do, it avoided the passage of trocars.

So does the Silimed in and of itself have any potential adverse effect? We don't know that because, to the best of my knowledge, there was not a group of women who had surgery without a product who had the support device only. So we don't have any information to say the vaginal support device is likely to be associated with any specific problems. It's just the predicate was used for a different reason.

Q. Well, and, in fact, one of the documents you were provided was the FDA Department of Health and Human Services approval letter dated August 5th of 1998 in which Silimed, LLC was approved under 510(k) as a Class II device, and it was determined it was substantially equivalent to the devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the medical device amendments, and, therefore, it was subject to the general controls provision of the food -- federal food, drug, and cosmetic act.

So there were requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding

and adulteration.

So do you have any complaints as we -- I'm trying to parse this to see what we have to discuss. Do you have any complaints about the Prosima or Prosima -- the vaginal support device portion of the Prosima device?

MS. THOMPSON: Object to form.

A. I have -- excuse me. I have no knowledge that the device in and of itself created a problem, because we don't have any information that the device was used without mesh. So I'm not -- I don't believe I'm opining about the support device as a standalone issue. It's simply used in association with a mesh product.

Q. (BY MR. WEBB) Did you see any reports of any adverse events or adverse reactions when it's used in conjunction with the mesh but that could be attributed directly to only the vaginal support device?

A. No, sir.

Q. I'm going to try to compare the opinions you have Prosima against the opinions you expressed in regard to Prolift and Prolift+M.

Your No. 1 opinion, "At the time of this introduction, there was insufficient scientific evidence supporting the implantation of the Prosima devices for pelvic organ prolapse."

That is the exact same wording except you have replaced Prolift and Prolift+M devices with the Prosima devices. Is that correct?

A. Yes, sir.

Q. And would your -- are we talking about separate timeframes here for when the Prolift and the Prolift+M devices came on the market compared to the Prosima?

A. They're -- excuse me. They're different timeframes. Excuse me. Gynemesh received 510(k) clearance before either of these, and then in the timeline, the next product that was developed was the Prolift without the M. It was Prolift.

So Prolift was developed, and then subsequent to that, the Prolift+M was a modification, and subject to that modification was the Prosima. And they were all separated by at least a year or more in between. So the Prosima was the last in that sequence of events.

Q. All right. Did the Prolift, the Prolift+M, and the Prosima all use the same Gynemesh?

A. They did -- with the exception of the Prolift+M, had a portion of the mesh that was absorbable. And the shorter name for the absorbable part is Monocryl, M-O-N-O-C-R-Y-L. There's a chemical

name, which is longer.

But the Prolift+M had the Monocryl, and that dissolved after a period of several months, and you were left with a smaller amount of the Gynemesh permanently implanted in someone.

Q. Did you see any -- let's compare the three. The complaints you had about the Prolift, did the Prolift+M relieve any of those complaints?

A. We don't have any information to indicate that that's true because the thing that's considerably different about the Prolift and Prolift+M is that they're both trocar based, and the product -- the arms that go with the Prolift and Prolift+M are still anchored in muscle.

The main difference with the Prosima is instead of arms, they have what are referred to as straps, and the straps are actually put into place, but the device that puts them in place does not penetrate the same muscle group in the pelvis. So it's a non-trocar based system using the same mesh. It just is placed in a different way, and it just doesn't end up with the mesh arms -- excuse me -- going through muscle spaces.

Q. Did you actually -- have you seen any comparison in the reported complications between the

Prolift, the Prolift+M, and the Prosima? I mean, is there any difference in the complication rates? Are there different complications associated with the products?

A. I think the general categories are similar. The idea behind the use of the Prosima is to eliminate the trocar use, and let's presume that part of the pelvic pain complaints are related to the mesh arms on the Prolift and Prolift+M going through a series of tissues, including muscle, and being left there and being exposed to vessels and nerves. And if that product then changes configuration, it may cause pain where the muscle has been penetrated, and it becomes very difficult to remove.

So as I understand it, the concept was to eliminate that portion of the procedure and simply lay the product against a structure in the pelvis and not penetrate a structure, because the Prolift and Prolift+M actually penetrated muscles and nerves in the pelvis.

And theoretically, there should not be the same type of complaints in terms of the mesh arms, but it doesn't eliminate or perhaps even reduce a likelihood of mesh exposure or mesh being approximated to structures and getting smaller and then pulling on structures that are innervated and resulting in pain or

in distortion of the vaginal canal. So those things still could happen.

Q. Did you do a comparison of the reported complication rates for each of these products compared to the others?

A. Not side by side.

Q. Off the top of your head, is there one that has less complications than the other, or do they all kind of fall into the same category as far as --

A. They are generally -- they're generally the same in the sense that both of -- both the Prosima and the Prolift and Prolift+M are both associated with mesh exposures. Both are associated with the surface area, the mesh, becoming smaller and causing contraction or scarification and banding, which can be associated with pain and alteration of the vaginal canal size. So those things are similar.

Q. Would you agree with the statement that any foreign body that's introduced in the body is going to cause some reaction, whether it's inflammation or scarring or collagen deposition or contracture?

MS. THOMPSON: Object to form.

A. By and large, all foreign bodies are going to create some type of response.

Under ideal circumstances, we could use a

product for a variety of things in the body -- it could be the eye, it could be the heart, it could be the pelvis -- that is totally inert and doesn't stimulate any excess reaction in terms of inflammation or scarring or anything else. That would be the ideal impact that almost never happens anywhere.

Q. (BY MR. WEBB) Well, in fact, it does not happen. There is no material that's completely inert. Correct?

MS. THOMPSON: Object to form.

A. Once it's implanted in the body, you would think it -- stainless steel, for example, you would think would be inert, but the truth is there still is a response because surgery, in and of itself, requires incisions and repair, and when the incisions heal, there's a cascade of events that occur, including, at least temporarily, inflammation.

Q. (BY MR. WEBB) Your second opinion about the Prosima device is the exact same opinion that you had about Prolift and Prolift+M, that they do not represent a significant departure -- they do represent a significant departure from traditional surgical procedures performed by -- for pelvic organ prolapse, and that they offer no advantage over a traditional repair. Would you agree with that?

A. Yes, sir.

Q. And we already talked about the -- what you consider traditional surgical procedures, and those would have been procedures that had been performed prior to 2000?

A. By and large, that would be correct. Some in 2000 -- or beg your pardon, 1996. Dr. Julian had reported on his use with Marlex, which is a synthetic wrap. So because his report was in 1996, obviously he began recruiting patients earlier than that, but he first reported it in 1996, but that was the exception. Not very many people were doing that.

Q. Do you consider that to be traditional surgical procedure or --

A. Without the use of mesh products, yes, sir.

Q. Was that product -- or is that product still on the market today?

MS. THOMPSON: Object to form.

A. Well, the Marlex, which Dr. Julian used, may be on the market. I actually don't know that. I don't believe that anyone uses it in any gynecological surgery, but could it be used for something else? It's possible. I wouldn't know that.

Q. (BY MR. WEBB) That was the sheep material. Correct?

A. Marlex is another synthetic sling. So it's not a biomaterial. There are biomaterials -- when I talked about Pelvicol earlier, Pelvicol is a biomaterial, and that morphed into several different things by a different company, but those came from animals. They're basically what's called a xenograft. Marlex was one of the early synthetic fibers that was made, and I don't know that anybody uses that in medicine anymore.

Q. No. 3, "The vagina is a different environment from the abdominal wall. Maintenance of vaginal compliance and distensibility is essential for bowel, bladder, and sexual function."

That's the same opinion that you expressed relating to the Prolift and Prolift+M. Correct?

A. Yes, sir, and that's because, again, the vaginal canal cannot be sterilized. That's one of the key differences. Plus, there were other qualities about the vaginal tissue that were important.

Q. And you discussed those earlier today, didn't you?

A. Yes, sir. Flexibility, distensibility, and sensitivity, and -- all those things. Excuse me.

Q. No. 4, "Insertion of the device containing

polypropylene mesh straps presents specific risk and is inconsistent with sound pelvic reconstructive surgical procedures."

That's different than the opinion that you had related to Prolift and Prolift+M.

"Insertion of a mesh device containing arms involving the blind passage of trocars presents specific risks and is inconsistent."

So Prolift and Prolift+M, you had the insertion of a medical device with -- by using trocars. You don't use trocars with the Prosima. Right?

A. Yes, sir, that's correct.

Q. And tell me what specific risks are associated with using a polypropylene mesh with straps rather than the ones with arms and the trocars.

A. I think there are several possibilities. Excuse me. One is in the dissection, getting into the proper space in the pelvis to place the straps, and that requires a sophisticated level of knowledge of anatomy and dissection. So getting to the desirable spaces to place the graft is one thing.

The second thing is once these spaces are dissected and the material is placed into the spaces and wound healing begins, access to those spaces is not as easy as it was the first time, and we know, as we

discussed earlier, foreign bodies invoke an inflammatory response. So even though there isn't a trocar, the local inflammatory response still occurs, and in these spaces which are developed, there still are vessels and nerves, and it's entirely possible that the mesh straps could form scar -- scar tissue in these pockets.

And if the mesh then shrinks, the mesh is going to pull on this area that's innervated, vascularized, whatnot. It may be a little different than going all the way through the muscle, but it doesn't avoid that all together.

Q. Have you, in your clinical practice, ever seen a patient that had Prosima?

A. Yes, sir. I've done an explant surgery, and when I gave you my earlier times that I acted either as a treating physician or an expert or a general report, the patient in whom the -- I was asked to be deposed as a treating physician of someone who had been treated with Prosima.

Q. That was Rabiola?

A. Yes, sir.

Q. Okay. And is that the one time that you've seen a patient with Prosima?

A. Well --

MS. THOMPSON: Object to form.

A. I know that for certain. There could be others.

What happens from a practical standpoint is we don't always have the opportunity to note, and the patients may or may not recall exactly what was done, and they may remember that something sounds like it began with a certain letter.

So let's say Prosima and Prolift start with the same letter, or something that sounds like it, Apogee or -- so patients get confused about that, and we actually don't know exactly what happened.

And you would say, "Well, couldn't you ask them about did they have puncture sites externally," which would help you decide that. And I do ask them that. And there are people who don't remember if they had a puncture site somewhere or not. They just don't remember that.

So I didn't have the operative note on a lot of these people. I know I had the one patient, Mrs. Rabiola, and I may have had others. It's just I can't tell you for sure how many.

Q. (BY MR. WEBB) And refresh my memory if I already asked you this, but did you -- you've identified at least some patients who had Prolift. Do you know of any that had Prolift+M?

A. No, sir, I don't know that. That was a later iteration of the product, and I would say without the operative note, practically no patient would remember that. If they remember Prolift, that would be great -- or the name of anything else, as far as that goes, not just Prolift.

Q. Did you see any medical literature that talked about the adverse events or the problems associated with the Prosima or Prosima product?

A. Yes, sir, two things. The one-year clinical follow-up -- or outcomes after prolapse surgery, which was published in 2010 in the American Journal of Obstetrics and Gynecology, Dr. Halina Zyczynski. So they looked primarily at vaginal support, so that's one. Their primary goal was not to look at other things, but, in fact, they did record other things about pain with balloon removal and pain after surgery. So they did look at other factors.

And in their discussion -- these are the authors themselves discussing their own manuscript, which most authors do, by the way. Most authors will look at their -- the strengths and weaknesses of their manuscript. That's one of the expectations that you would do.

And these authors said that the absence

of a comparator group -- which means someone had a similar surgery, same group of people -- they didn't have one of those, so it's hard to know how the outcomes in terms of pain and other issues compare to what they would normally do without mesh.

But they didn't have -- another outcome that was reported by Dr. Sayer, S-A-Y-E-R, as the primary physician, and included Dr. Slack, who was one of the earlier users, all a part of what's called a Prosima study group, and they looked at outcomes of surgery. And it was designed to evaluate women who had to have at least two years of follow-up.

And that's what they wanted to report on. They describe the type of people they operated on, the product that they used, and then looking at anatomical outcomes, that was their primary outcome measure, which is what most authors have had, quite frankly.

Then they looked at mesh exposures and need to be reoperated for recurrent prolapse. So that was at a minimum of two years after surgery, and these authors referred to that as medium term -- we had spoken earlier about long-term outcomes. So two years or more is actually much better than six months or 12 months. It's still referred to as medium term.

And the other thing I think the authors

pointed out is with these -- with this procedure they're specifically referring to, there's a learning curve, and, in fact, that happens with all surgery. There's a learning curve that goes along with it.

And again, they comment on their own study saying that their major concern is they don't have a control group who was operated on without using either the support device or the mesh.

So all the authors recognize that, and the truth is what they're primarily looking at is a group of women who have the -- this case, the Prosima, which is the mesh and the support device, and they're looking primarily at do they get better anatomical outcomes.

And when you and I talked this morning, one of the stimuli for wanting to find something helpful is to reduce the likelihood that a woman will have surgery for poor support and not have the best opportunity to get that poor support corrected. So all of them want to improve the anatomical outcomes. That's the goal of all of these things.

Q. And does it appear that they did have more success with the anatomical results?

A. Yes. It depends again on how strictly someone defines "success." They had really rigid criteria for

anatomical outcomes. The success rate isn't as high as if they use a more clinically applicable outcome.

And in general -- this applies to these authors, and in general to most authors. What they find is that if you use anatomy in what's called the treated compartments -- so if it's by the bladder or the rectum and you treat those -- use anatomy in the treated department, as a generalization, the anatomical outcomes are equal to or better than not using mesh. So that's one outcome variable.

What has become apparent in these different products that have been used, two things. One is the untreated compartment. So let's say there are two or three places in the pelvis that could require surgery, but today the woman really needs surgery in one compartment.

What we are learning is that that one compartment is treated with a mesh product, that the longer you follow her, the more likely the untreated area may prolapse out, or something adjacent to where the product is may prolapse. So that was sort of -- that was not necessarily anticipated. So that's one thing.

And the other thing that they are looking for is not just anatomical success. It's how many

people have erosion, bleeding, with a mesh product.

So when they report outcomes, in general, authors are going to say that if you use anatomy as the endpoint, that mesh products in the anterior compartment specifically have a better anatomical outcome than non-mesh. The follow-up -- the extension of that is the quality of life in patient subjective satisfaction is generally equal in mesh and non-mesh product surgeries.

The third area they look at is requirement for reoperation for any reason. And almost universally what all authors find is the need for repeat surgery is greater in the women who have mesh than the women who don't.

And the indication for repeat surgery could be recurrence of the prolapse. It could be pain. It could be exposure of the mesh. But in the aggregate, women who have mesh end up having more likelihood to have surgery than someone who didn't.

So then what some people look at is they say, well, since the anatomy is better, how do we quantify what we would have to do in order to say that it's really a good idea to use the mesh product?

And if you said you used mesh products on everyone, for example, what you would find is that for prolapse, for example, you would have to put mesh in

anywhere between six and 19 additional people from what you're currently doing, six to 19, to reduce the likelihood that one person would have more surgery. In other words, one out of six would be 15 percent. One out of 19 would be 5 percent. So you'd have to treat a lot of extra people with mesh to minimize the likelihood that if they didn't have it, that they would get recurrent surgery.

So I don't think anybody -- this is my assessment of it. You asked me earlier, I think, about if I look at the literature. I don't believe that anyone is disputing that in the anterior compartment of a vagina, mesh can offer a better anatomical support.

In the posterior compartment, in the top of the vaginal canal, that is probably not true. It is probably not better than. So with the anterior compartment, the anatomical outcomes may be better.

What we also know is exposure occurs in the anterior compartment, or the posterior, either one. So we know there's mesh exposure, and we know that for almost all authors, the reoperation rate is greater when you use mesh, global reoperation rate.

So for some women, there are benefits. Other women, the cost of having it is greater than the benefit.

Q. Item 5, "There were no studies prior to the introduction of the Prosima device demonstrating safety and efficacy of the vaginal support device - balloon assembly."

Do you know what kind of studies were performed on the Silimed vaginal stent?

A. Not by itself. I'm not sure -- excuse me. I don't know if there were any efficacy studies on Silimed, quite frankly, because it was indicated for such a defined group of women that it would be -- it's possible, but I'm not aware of it, that someone would be able to look at a group of women who were treated with and without the Silimed device. I don't know that, and I don't ever remember hearing that discussed anywhere.

Q. Your Item 6 is the same opinion, "Traditional surgical repairs are effective. The medical literature does not show improved outcomes with the use of the Prosima device or any other transvaginally placed mesh."

That's the same opinion you had with Prolift and Prolift+M?

A. Yes, sir. Dr. Carey himself actually showed that.

Q. Well, you say it does not show improved outcome. Does it show comparable outcomes?

A. I think in the aggregate, if you look at the

anatomy, they're probably very comparable. If you look at reoperation rate, which I mentioned before, they're not comparable, because in any women who has mesh placed in the vagina, there is an almost irreversibly low likelihood that she will get mesh erosion and require either medical treatment or excision of the mesh.

So in that sense, the anatomy could be similar, but the reoperation rate is going to be higher, and that's been reported by all authors in women who have mesh. Excuse me.

Q. What about other complaints like dyspareunia?

A. The other complaints are not easy to determine, and there are reasons for that. For one thing, unless the author has set up a prospective study looking for a lot of variables, women who have any kind of surgery, with or without mesh -- so if you ask them about their pain complaints after surgery, pain with intercourse, pain with surgery, pain with anything, it doesn't really make any difference -- if you didn't have a baseline for that same variable and have an answer for it before the operation, then what happens is called recall bias.

So if someone were to ask me what happened three months ago, I may or may not remember that. If they ask me a year ago, I'm less likely to

remember. So all that information needs to be collected prospectively, and, in fact, it generally isn't.

There are one or two articles that were in that previous report on Prolift from Dr. Anne Weber, who was at the Cleveland Clinic, who tried to look prospectively at the specific sexual complaints before and after surgery, but it wasn't in the context of using mesh.

I think all of us agree that women can have pain following surgery. The issue is, partly, how can you manage that pain and what seems to be associated with it in the absence of a mesh product. You're dealing with a certain set of issues. It could be a trigger point. It could be a scar is tender. It could be a variety of things.

Once the mesh is introduced, the mesh itself may be associated with the pain instead of a local inflammatory reaction. So it wouldn't necessarily be that a woman would have no pain if they didn't have mesh. I don't think anybody says that. It would be they have a different kind of pain, and the management of it is potentially much more problematic.

Q. List for me what severe life-changing complications that are not seen with traditional pelvic reconstructive surgery that you find with mesh, unless

you've already gone through them.

A. No, sir. I haven't answered that for you. In the referenced articles, which are in my Prolift report, there are two reports from the University of Utah, and Dr. Ingrid Nygaard is one of the authors on both of those reports in our professional journals, and one of them provide free text, so women are allowed to describe what's happened to their lives when they develop these complaints.

So the life-altering ones that are in one of her articles says that women who acquire these complaints fall into three categories. One category is they acquire pain, they see someone, they're managed, and for all practical purposes, they don't have significant complaints after that.

There's another group of women who acquire pain complaints, and they're treated, and their complaints don't go away, but they acquire a new sort of baseline activity in their lives that is reduced -- their quality of life is reduced from before, but it's more or less stable.

And there's a third group of women in whom they acquire pain complaints and they have an intervention, and they are caught in what this group has called a downward spiral of their health, or the other

term they use is their life has been spoiled by pain, and that's what the patients describe. They can't do their normal activities. And once that happens, there's a whole cascade of events that affect their relationships with their sexual partners, their family, their job, their everything.

So there are those people that have this downward cascade. There are those that reset to a lower baseline. And this isn't the same thing, so I'm not purporting that it is. But my personal observation of that in my own family -- not with mesh, but I'll tell you who how people reset a baseline. My wife who died had rheumatoid arthritis, and in order to function normally, she had to reset a baseline of how to work. Because you can't expect to do everything you did before. You're going to be disappointed. You have to reset what you're capable of doing.

And in this case, that's what some of the women with mesh have done. They've reset their baseline at a lower level than before.

That's when I say life altering. That's what I mean by that.

Q. Give me an approximation of the sizes of these groups, these three groups you're talking about.

A. In this group that was reported from the

University of Utah, I want to say that the ones who responded and felt better and the ones who reset their baseline were more or less equal. So I'm going to make these percentages up, because I don't remember the exact percentage, but it's close to accurate -- that about 40 percent fell into each of those, and there's in the neighborhood of 20 percent who have this continuing spiral of they hurt, they feel bad, it affects their job, their relationship, and all those things.

Q. Okay.

A. That's a selective group of people who have come specifically because they have had complication of their prior surgery. I'm not suggesting that 40 percent of all women who have the products have pain and get better and 40 percent reset and 10 percent are on a downward spiral. I'm referring to the group of people who were bothered enough to come to the doctor to seek intervention because of their pain complaints.

Q. Any other life-changing complications that you have not described earlier?

A. Well, the -- one of the things I would consider to be life changing is the requirement for multiple interventions, and the interventions could be physical therapy, for example.

Well, how does that change your life?

Well, it means -- depending on what you're capable of doing, you have to get transportation to and from wherever you're going and spend a certain amount of time there. So there's a time commitment to that over an extended time period. That's at one level.

Another level is the multiple surgeries, and the multiple surgeries involve everything that could go the matter with surgery, including anesthesia, the recovery, the expense, the time lost for wages, however you calculate all those things. But if you have one surgical intervention, there's a certain level of time away and cost associated with it, but if you have -- in the case as of some of these people, multiple -- when I say "multiple," I mean more than two -- where they have multiple times where they are having to have surgery and miss work and recovery and whatnot. That's life altering.

The other one which affects people in general is their relationship with their spouse or their partner, so -- all those things happen that really -- they change the dynamic in someone's life.

Q. Well, it sounds to me like what you've just described is going to be case specific to each patient.

MS. THOMPSON: Object to form.

A. Well, I think part of the point is what you've

said. People respond differently to different things, and we are learning more about that as we -- as people learning about diseases become more sophisticated, that we may not all respond the same way to some particular event in our lives.

In the future, we may be able to do that, but we don't now. So you may say in the case of surgery of any kind that someone may respond and do beautifully and have very few complaints regardless of whatever the surgery is, and other people are at greater risk for having an adverse outcome from surgery.

We can't -- we -- we know that transpires. How do we go about picking them out? There are some clinical clues, so -- we know there are clinical clues to that.

Q. (BY MR. WEBB) Mesh removal surgery being complex, is there any difference between Prolift, Prolift+M, and Prosima?

A. Yes, sir, there is. When the mesh arms go through either what's called the sacrospinous ligament or the muscles in the pelvis and the wound heals, getting all of that mesh product out really requires, for lack of a better term, injury to those structures again. Because you have to incise and cut into the structures where the mesh arms have been implanted.

From a technical standpoint, that would be on a scale that's more difficult than someone who has a product lying against a surface area. There still is the difficulty of the dissection to identify the product, but when it's adjacent to something and you don't have to go into the structure to get it out, the degree of technical difficulty in general should be less.

Q. Okay. Characteristics of polypropylene mesh when implanted vaginally for pelvic organ prolapse include chronic inflammation.

Was chronic inflammation warned about in the product warnings?

A. You know, I don't remember if the specific term "inflammation" was used or not. I know that it says the mesh can erode, they can have pain or infection. I'm not -- I don't remember clearly if it says "inflammation." I don't know that.

Q. How about foreign body reaction, or do you think it's even necessary to warn about foreign body reaction?

MS. THOMPSON: Object to form.

A. Well, you asked earlier, well, am I an expert on product information and whatnot. I am not an expert on that, but I would say, in general, patients would be

looking for something that's much more in their own vocabulary than "foreign body reaction" or "granulation."

Q. (BY MR. WEBB) For example, it could cause pain?

A. Painful, inflamed. Most people know what inflamed -- so that's not the same as inflammation, but around -- in one sense, it's very similar.

Where those products are, the tissue around it is inflamed, or inflammation, maybe, is the best term. I don't know that.

But in the people I deal with, in general what has been shown is for all educational things that you and I do, whatever -- whatever it is, it doesn't make it any difference -- you would like to have it at a level so somebody who is in the 8th grade could understand it, and currently that's not a very sophisticated level.

Q. Do you get fibrosis and scarring with the implantation of any medical device?

MS. THOMPSON: Object to form.

A. I am -- do you get scarring with any? Anytime there has to be an entry point to do something, yes, there will be a scar formed.

So if you have to puncture it, cut it, do

something to it, the body's reaction is to heal through scar formation. So, yes, that would happen, whether it's an accident or it's a planned surgical intervention, either one.

Q. (BY MR. WEBB) You're not saying that every patient is going to have every one of these characteristics, are you?

A. No, sir. And I'm saying that some patients won't have any of them.

There's a -- the way clinical follow-up appears to occur, the authors who report on adverse events by and large are subspecialists working in referral areas, such as I do, or such as the group at Utah or the group in Cincinnati or Ann Arbor, Michigan. It's generally a referral group.

And what we see in them is, in general, women who have an adverse outcome are more likely to go to another doctor than they are to the doctor who performed the original or the index surgery.

What that does, then, is once the patients either self-select or perhaps are even referred by the treating doctor -- it doesn't make any difference. But when they self-select, doctors who are in the practice such as I have are more likely to see someone who isn't happy with the outcome, and the

doctors who like to use whatever the technique is may only see their patients back who are happy with it, and they may not see the ones who have had an adverse outcome. And then the impression is reinforced that actually this works better than most people say because I don't see my patients back complaining.

The caveat on that is just because you don't see a patient or I don't see my own patient -- just because I don't see them doesn't mean that there isn't an issue. And we know from reports in the literature that between 60 and 80 percent of women who have adverse outcomes are more likely to go see someone who did not do the primary surgery.

Q. Ethicon did not provide doctors and patients with complete and accurate information regarding the efficacy, safety, and complications associated with the Prosima devices and their management.

That's the same complaint that you had about Prolift and Prolift+M. Is that correct?

A. Yes, sir, that's accurate, because there was not a way to do that. The duration of follow-up had not lasted long enough. The factors that were getting followed were relatively narrow in terms of anatomical outcomes and perioperative morbidity, so it wouldn't be practical to collect enough information in those

circumstances to be well informed enough to tell either the implanting doctor or the patient who is receiving the product exactly what to expect.

Q. And these are the same complaints that you made earlier about the Prolift and the Prolift+M?

A. Yes, sir.

Q. And let me try to summarize it. You complain about the lack and the length of comprehensive study of the patients?

A. Yes, sir.

MS. THOMPSON: Object to form.

A. So the way I interpret what you're commenting on is there wasn't a plan put in place to investigate enough of the variables that relate to -- this is antecedent to the surgery -- who is a good candidate for the surgery, who is the best candidate for the surgery, who is not a candidate for the surgery.

The information given and the information for the users is very limited on contraindications. So what's become obvious to the majority of clinicians that isn't in the IFU, for example, or certainly wasn't, is there are a group of people that are outside what was in the IFU. There are people that are older than 18 or 21, that are not pregnant, they're not going to be pregnant, they don't have an active infection. Those are the

things in the IFU.

What they do have, they have a history of fibromyalgia. They smoke excessively. They have diabetes mellitus. They have a variety of other pain complaints, and none of those were isolated out as a potential contraindication to the use of the predict.

And I would say that currently, even the most avid advocates of using the products, presuming they were all still available, would come to some consensus that there's a group of women that can be identified by their history who are at high risk for being unhappy with the product, and that those people justifiably need to be advised to consider something else. So that's in the selection criteria. That's not the follow-up.

The other thing that has been almost nothing written about is not do you have a complication, it is how do you manage a complication. What's the best way to manage a complication and, ideally, to avoid?

So it's a preoperative selection process or elimination for people who are not candidates. It's the identification of a person who is most likely the benefit. So let's presume there are people who do get better. The obligation, then, is let's identify those people. Then we can sit down and have a conversation

with them and feel comfortable that we could say, you know, based on what we know, you actually are a better than average candidate to have this done, but even though you're better than average, these are the things you might expect, and if it occurs, I am capable of managing certain of these things with some degree of knowledge about how likely you are to get better, and we don't have that.

In addition to, some of the things that are problematic, which were unintended, don't show up immediately, and once you have a foreign body in you, you're at risk for that event to occur for the foreseeable future.

And I can say that in seeing my own patients now -- because I do have a clinical practice of medicine -- is that there are a group of people who are anxious to know, "What can I expect? Today perhaps I don't really have a complaint, but I know that people have had them, and can you counsel me on what's going to happen?"

People want to know that. And that would have been a helpful thing.

Saying that someone has pain is one way to say if you have the surgery, you can have pain. Saying that you may have pain that is lifelong and

affects the quality of your life and it's practically impossible to manage is a whole different issue.

And, in fact, we do see there are people that fall into that category. I'm not suggesting everyone does. I don't think anybody suggests that, but there are enough that when you pick up the literature, the group in Cincinnati had 300 patients, the group in Michigan had a hundred and something, the group in Idaho -- or Utah had a hundred and something.

So there really are a lot of people who have sought attention from experts, and I have no earthly idea, frankly, if any of them or any percentage of them have actually sought legal counsel because of -- they're coming to a doctor because they're -- they need some advice on how to get better.

Q. (BY MR. WEBB) Well, you also know that there are women who have gone to lawyers and then go to doctors after they've been to lawyers?

A. Yes, sir.

MS. THOMPSON: Object to form.

Q. (BY MR. WEBB) Have some of your patients been those type of women, who were referred to you by lawyers?

A. There have been some women whom I have seen who before they come for a visit, there has been a

request sent to me that if they have explant surgery, could the explant material be provided to a lawyer or a particular hospital or somebody for an evaluation. So I have seen patients like that.

And they may, in fact, have consulted with somebody in advance. I don't know how many do that, but, yes, some people do that.

Q. And do you have any idea, out of the 100 patients that you have seen with mesh, how many were referred to you by lawyers?

MS. THOMPSON: Object to form.

A. Actually, I don't know that. I would say my practice is primarily a referral practice, and that's based on a lot of things, almost the least important of which is being referred by a lawyer. It normally is for other reasons. Either they have someone they know that I've cared for or their doctor is someone that I've worked with or know or they've read about it somewhere or another.

So the exceptional one would be the one who says that my lawyer asked and gave me your name among, whatever, maybe one name or several names, to be seen.

Q. (BY MR. WEBB) Ethicon failed to disclose the lack of benefit of pelvic organ prolapse surgery using

the Prosima device to physicians and patients.

For any medical -- well, for any surgery, there's risks and benefits that have to be analyzed on a patient-by-patient basis. Would you agree with that?

A. I do.

Q. Do you think that the risk with Prosima outweighed the benefits for most patients?

A. Yes, sir.

Q. And have any of your fellow practitioners in your practice used the Prosima device?

A. No, sir, not that I know of. I will say that in general, when I counsel a patient -- and I've already told you I don't use mesh products for reconstructive surgery. We do do an abdominal sacrocolpopexy.

When I counsel a patient, it isn't that I tell them that what I can do is magic. I try to point out a reasonable set of expectations. And an example I would use -- and I use it frequently, particularly when I'm lecturing somewhere -- that one of the easiest hernias in the world to fix is in the inguinal canal. So if you or I or anybody in the room or your child or somebody has an inguinal hernia, that's among the easiest operations to do technically.

It doesn't work all the time. It will never work all the time. And the only goals for that

surgery, primarily, are to fix the hernia and, unless the man wants it, don't remove the testicle or tie off the vas deferens. So don't do those things unless they request it.

So, from that standpoint, there are very specific outcome parameters, and it doesn't work all the time. And the two biggest variables outside surgical diagnostic skill and technical skill -- so let's presume they're equal -- the two biggest variables to outcome are how big was the hernia at the beginning, and how long do you follow the patient. So the bigger it was, the more you'll follow them, the more likely they're going to have a recurrence.

In women who have problems with the pelvic floor, the issues are considerably more complex. Their bladder may not work. The bowel may not work. Their muscles may be injured. Their nerves may not work. The connective tissue may not work. And they may want all of that to be okay, and for a lot of people, that's a reasonable expectation.

There isn't anything that works all the time for every person, and I think all of us recognize that. And everyone recognizes we would like to be able to do better in the context of not causing harm.

So we want to do better. We don't want

someone to be harmed, and all these issues that I have in the general report which you asked me about relate to the fact that there wasn't enough knowledge acquired and/or shared to be able to tell someone, "Not only are you likely to get better, but what is the likelihood that you could be harmed? And if you are, what's the likelihood we can help you with that?"

Those are reasonable things that people would -- I would want to know that. You would want to know that. So those are reasonable things, but we don't have the information on that. That's the -- that's my primary concern.

Q. Describe for me a scientific clinical trial demonstrating the safety of the Prosima device that should have been done before its introduction to the commercial market.

MS. THOMPSON: Object to form.

A. My thought about what would have been helpful to be done is to describe a group of people --

Q. (BY MR. WEBB) How big a group? How big a group?

A. There's something called a power analysis that can be done. So the power analysis determines, based on what you think the outcomes are -- for example, if an operation fails 20 percent of the time -- so whatever

the failure is, whatever we call failure, if it fails 20 percent of the time and you want to be able to reduce that failure rate by 10 percent -- I'm sorry, by 50 percent, so instead of failing 20 percent of the time, it fails 10 percent of the time.

So if that's your goal, there is something called a power analysis that can be calculated to tell you that to learn that, presuming 20 percent of the people have an adverse outcome, and you're going to have some people you treat one way and some the other way, you will have to recruit -- I'm making this up, but I'm going to give an example -- you'll have to recruit 200 women, because if you recruit 200, actually 20 won't qualify or won't agree. So you'll end up with 180.

Now those 180, you get that 90 in each group, and then you have the power to make a statistical assessment of are those operations similar or not. And depending on the number of variabilities you have, that would determine how long you would have to follow those patients.

In my patients -- in an article in 2000, for example, which was not randomized, and I recognize that, it was a group of women I followed, basically 300 women, and I had in mind certain variables, but one of the variables which was really important to me -- and it

is to this whole issue -- is how durable is an operation?

So if I agree to be operated on, how long can I expect my -- my knee's replaced. How long can I expect it to work? Is it a year? We know what happens -- actually, it's a function of time, so the longer you go, the more likely it isn't going to do whatever you wanted it to do.

But until we reported that in this special statistical analysis called a Kaplan-Meier table, it really hasn't been reported in reconstructive surgery. Now, almost everyone uses it to say, "This is the durability of the surgery." That's one important issue.

The other thing we've looked at -- and we've learned this as time has gone by -- there are going to be adverse events with surgery. There is no way to avoid that.

My mother died after an operation, so I'm acutely aware of that. There are adverse events after surgery. What I want to know, can I avoid it, and if I can't avoid it, how can I identify it and correct it? So we are learning about that.

And what I do, I know that there is a little group of women who will acquire a pain complaint

they did not have before surgery, and it is specific to what I do, and I know when it shows up, and I know the presenting characteristics, and I know how to take care of it.

So if I talk to someone about that, I can say, one woman out of 100, about, will have this very specific adverse event, which I can recognize and I can tell you how to manage it, but I cannot avoid it. I cannot avoid it all the time. It's not possible to do that.

And when the patients know that, even when they have the adverse outcome, they have the knowledge that that's something I really do know about, and if it bothers them, I can manage it. That's a comfort to the doctor and to the patient. And in these circumstances, the thing that's different is these are complications that in general are different than what we've seen before and, frankly, doctors are still working out how to manage them most effectively.

There's a whole spectrum of thought on that. If you have pain after mesh, some doctors advocate taking out the entire mesh. Well, the truth is there's a tiny group of people technically skilled enough to do that without really creating a problem. And even if they are skilled enough to do it, there

still is a risk that what they do will make the patient worse than they already are.

So we are still working on how to identify and manage it, and that's the dilemma. And I don't think I'm suggesting that that was a conscious decision on anyone's part to say, you know, we're going to hurt people. I don't believe that. I don't think anyone wants to do that. But the unintended consequence is people were hurt and could you -- could, not you personally -- could people have anticipated that? Frankly, probably not eliminated, but done everything possible to make that less likely to occur. And if it were to occur, to have a strategy to manage it.

And this is something I know a lot about because I see these people, and, frankly, the people I see almost never have come to me saying, "I want to sue someone."

That's the exception. They come to me with their spouse because their life has been changed.

MR. WEBB: Objection; nonresponsive.

Q. (BY MR. WEBB) Tell me the length of this hypothetical clinical trial that Ethicon should have put in place --

A. Well --

Q. -- to demonstrate the safety -- let me finish

my question before you start.

A. I'm sorry.

Q. Tell me the length of this hypothetical clinical trial demonstrating the safety of the Prosima device that should have gone on before its introduction to the commercial market.

A. Depending on the outcome variables, it's possible to understand the perioperative complications very quickly. So then you just have to decide how many people do you need to recruit to do it. So the perioperative complications can be done quickly.

The issue about picking the right patient and have comparable groups -- so you've used the same selection criteria, and then if you're looking for the onset of anatomic failure, most of the anatomical failures that are not technically related -- that means the operation wasn't executed well or was underdiagnosed -- so if you eliminate the immediate postoperative failures -- so somebody is in surgery today and a week from now or a month from now the surgery hasn't worked. So let's eliminate those.

Now it's somebody who had initially a good response but have a recurrence. That takes at least one year, and even that probably isn't right. Several years, depending on what people -- that's for

the anatomy.

Then because some of the problems are actually not known about -- they may be anticipated but you don't know them, pain complaints, contraction of the mesh, and if it contracts, how long does it take to create a problem -- you can't really know that until you set an arbitrary time limit, and that could be one year or two years. But what most doctors would then do who are involved in a trial, they would say, "Well, I'm going to follow these patients later because what I may find out is all of the problems came up in the first six months, then after six months, there really is nothing," or, "What I really found out is some of them came up at six months or a year, but, you know, really, the longer we followed them, there's some other things."

So that's not practical, to follow somebody indefinitely, but somewhere between 12 and 24 months would be a reasonable start on that, along with strict criteria on the patients for whom you can use the procedure.

Currently, when I read these reports in both the Prosima and the Prolift, it could have been for a woman who has had prior surgery and failed, a woman who has had no prior surgery, a woman who has a hysterectomy, a women who doesn't have a hysterectomy, a

woman -- so the variables just mount and mount up, and one of the issues which these documents have shown is: That's important to know, are they going to have a hysterectomy and, what kind of incision? That was learned on the fly, sort of.

So there are so many variables to look at, but if you just pick a few of them -- selection, avoiding complications, managing complications, anatomical outcome, acquisition of complaints -- that would take at least, for recruitment -- the recruitment would take at least a year. The follow-up would take at least a year. And then, depending on how you do the power analysis, the recruitment could take longer.

That's one of the issues now with these 522 things that some companies are going to do is the power analysis tells them they have to recruit so many people, that one surgeon can't be -- can't do it. It has to be a multicenter study to do it. Those things all add complexity and expense to it.

Q. Out of the 100 patients that you've seen who have had complications with mesh, how many of them do you think are surgeon's technique problems?

A. I wouldn't allocate the technique problem, frankly, to any of them with the following exceptions. If I see someone -- or someone I operate on, let's

say -- so I'm not always pointing -- to say somebody else did it. I could be the one who does that.

For example, this one article you asked me to confirm earlier today about placing a TVT in the bowel, that was my patient. So it wasn't somebody else's patient. It was my patient.

So the surgeon contribution to the problem frequently is identified immediately. The product is put in the wrong place, in the bladder or in the bowel. When I say "immediately," either right then or within the next day or two. So there can be a surgeon error. There's no doubt about it.

The other thing that's much more subtle, which this anatomic report in the Prosima, where they took a group of people and took them to the anatomy lab, that's much more subtle because you are having a surgeon operate in a space where you cannot see what they're doing.

And I taught cadaver labs, and I've operated on thousands of people. A cadaver lab and operating on real people have some similarities, but doing vaginal reconstructive surgery on a cadaver -- and some of these cadavers are 90 years old or 92 years old -- that is extremely difficult to -- not only to do, but for a teacher to watch someone else and effectively

teach them what to do, that's challenging.

MR. WEBB: Objection; nonresponsive.

Q. (BY MR. WEBB) You said you personally have examined, diagnosed, and treated approximately 100 patients with mesh complications and removed some mesh from at least 70 women.

How many out of those patients are -- do you think are directly related to physician technique?

A. What I tried --

MS. THOMPSON: Asked and answered.

A. I'm sorry. What I tried to explain is what I think would be a physician error, and the ones that I know are physician errors, I haven't seen them, where the mesh was put into something.

Q. (BY MR. WEBB) So you're saying zero out of the 100. Is that what you're saying?

A. No, sir. What I'm saying is --

Q. I'm asking you for a number, Doctor. If you can give me a number, say it. If you can't, just say you can't give me a number.

MS. THOMPSON: Objection.

Q. (BY MR. WEBB) We're going to be here until 9:00 at the rate we're going.

A. I don't --

MS. THOMPSON: Objection to that --

A. I don't know. I'm sorry.

MS. THOMPSON: -- comment.

MR. WEBB: Well, there's a point when if he's just going to sit there and just -- you know, just blabber and not answer the question, then I'm going to cut him off. Do you understand?

MS. THOMPSON: I think you can cut him off, but we're not going to be here until 9:00 regardless.

MR. WEBB: Let's put it this way, then --

MS. THOMPSON: We're going to be here --

MR. WEBB: -- I'm going to keep going until the maximum time, then, if that's --

MS. THOMPSON: Okay. Well, you've got --

MR. WEBB: -- the way we're going to play the game.

MS. THOMPSON: -- two hours, and we'll go the two hours.

MR. WEBB: No. I've got three hours is what I've got on each one of these.

MS. THOMPSON: No. You have three hours on the first and two hours on the second.

MR. WEBB: Okay. Well, I -- we'll go until every minute of it is gone if that's the way --

MS. THOMPSON: Okay.

MR. WEBB: -- you're going to play it.

MS. THOMPSON: All right. You've got about --

THE WITNESS: I'm comfortable -- if I'm not answering effectively, tell me. I'm fine to stop and try to answer it. I'm not trying to avoid your question. So I'm happy to try to respond, and just ask me to do that.

Q. (BY MR. WEBB) Tell me why Ethicon did not exercise due diligence in the design and development of the Prosima mesh.

A. I think it's the things we've mentioned already about the unknown, putting something in these spaces and leaving them there and what the potential benefit or non-benefit is to putting a support device in it.

Q. Tell my why Ethicon lacked scientific rigor in the testing and reporting of its pelvic floor products, including the use of Gynemesh.

A. Because we don't have the information about prospective clinical trials on how the products behaved in people.

Q. Ethicon did not heed the warnings from the hernia and gynecologic literature relating to the use of polypropylene mesh?

A. The hernia wall -- the abdominal wall or the inguinal canal are sterile areas, and mesh is used in a sterile area. And if it -- if there's wound infection, mesh isn't used in those areas. And the vaginal canal isn't sterile. It's contaminated.

So those are major differences. And there have been reported incidences of mesh shrinking in the abdomen and pain associated with it.

Q. If Ethicon had properly tested its products, certain problems and complications would have been identified before they were used in a clinical setting.

Tell me, if you haven't already, what problems and what complications would have been identified before they were used in a clinical setting.

A. Well, from a clinical use, so the clinical -- the evaluation before clinicians in general used them would be more knowledge about erosion rates, pain, contraction, and possible effects on bowel and bladder function. And in the case of exposure in the vaginal canal, possible injury to the sexual partner or new onset pain complaints.

Q. "Ethicon inappropriately marketed its prolapse mesh products to all physicians."

Is this the same answer that you would give me as you did on the Prolift and Prolift+M?

A. Yes, sir. People have varying skill levels to use -- and this is a sophisticated operation, and there are varying skill levels, and people, frankly, don't have the skill to do that.

Q. And you said earlier -- this says, "Ethicon inappropriately marketed its prolapse mesh products to all physicians."

Yet you told me that the hospitals were the ones that bought the products. Is that correct?

A. Yes, sir.

Q. And --

A. I beg your pardon. The hospital may buy it at the request of the physician, for example. I just -- I don't think there's a direct transaction between the doctor and --

Q. Well, and it also may be that hospitals enter into contracts and they tell you what products are going to be made available to you. Correct?

A. That's entirely true.

Q. "After the products were used in a general clinical setting, Ethicon did not systematically monitor their products for safety or efficacy or evaluate physician feedback."

What do you base that statement on?

A. I didn't see any documents to indicate that.

Q. Did you ask for any documents on that?
A. No, sir.
Q. Were -- did you ask the plaintiffs' lawyer, who provided documents to you, to give you documents specifically about Ethicon's monitoring of the products for safety or efficacy or evaluate physician feedback?
A. No, sir.
Q. The problems associated with the Prosima device are inherent in the concept and design and occur even when the device is placed properly.
Is this the same complaints that you had about the Prolift and the Prolift+M?
A. It's similar because it uses the same mesh product. The -- the placement is different, but it's still the same mesh product.
Q. Is there anything about the placement that would be different about the Prolift or Prolift+M?
A. Yes, sir. Theoretically, it would be a safer placement for Prosima.
Q. Why do you say, "In Carey's randomized trial comparing traditional anterior and posterior surgery with the Prosima precursor, the authors failed to demonstrate any improvement in the treatment of prolapse"?
A. Those are his conclusions. Well, I mean, when

you look at the data, that's -- that's what it showed. He showed approximately a 20 percent persistent anatomical defect in both groups of patients.

So there were -- it was a randomized trial in which it didn't show that one was appreciably better than the other.

THE REPORTER: I'm sorry. It didn't --

THE WITNESS: It was a randomized trial which did not show that one was appreciably better than the other.

THE REPORTER: Try to keep your voice up for me, please. I'm sorry.

Q. (BY MR. WEBB) You make a statement saying that, "During implantation, tension is placed on the mesh as the instruments are placed in the pockets of the straps, not only during implantation, but after the Prosima straps are put under some tension, which may ultimately lead to mesh bunching, wrinkling, deformation."

Do you know whether or not that actually happens?

A. I don't know --

MS. THOMPSON: Object to form.

A. I don't know that it happens every time, but I know from the standpoint of, for example, using a

midurethral sling, which I've done hundreds of times, that it -- what you intend to do doesn't always go exactly the way you want to do it. So the mesh may lay flat temporarily and it may not, and you have to manipulate it to get it into position.

So it isn't -- it doesn't always lie exactly in the position you would like it to be, and when you work with it in a space where it's actually remote from where you can see, you have to put some degree of tension on it in order to try to flatten it or straighten it out.

Q. (BY MR. WEBB) Have you actually read the Prosima IFU?

A. Yes, sir.

Q. When did you read the Prosima IFU?

A. I read it twice. I read it sometime back in January, and I read it again over the weekend.

Q. Is it in the documents that you provided us today?

A. I thought it was, but it may not be. I may have taken it out, actually, and failed to put it back in there. But the answer is, yes, I did read it and I highlighted it, and I thought that I had put it in here, and what may have happened is it may be in my study at home.

So it's possible I -- I apologize. I didn't look specifically for that, but I did read it. There was information for use, which I highlighted and used that in preparing the report.

Q. What did the IFU say about the use of this product in women with a history of chronic pelvic pain?

A. I'm not sure it said anything. It said do not use it in women with vaginal infections. It said that the product stays soft and pliable. I don't recall that it said anything about the use in women with chronic pelvic pain.

It commented on using the product in women who have certain degrees of pelvic organ prolapse, but that degree wasn't specifically quantified, nor the reference point for its -- what was it, for the POP-Q stage, or was it something else -- which people would use in common language to know which candidates are best.

MR. WEBB: Let's take a short break.

THE VIDEOGRAPHER: Going off the record, the time is 2:49.

(Recess from 2:49 p.m. to 2:56 p.m.)

THE VIDEOGRAPHER: Back on the record. This marks the beginning of Disc No. 4. The time is 2:56.

Q. (BY MR. WEBB) Dr. Shull, the time that you spent with an attorney representing the plaintiffs, did you include the time that you were talking about Prosima in that time? Was that total time?

A. Is that on the time sheet that I gave you there, or is that for other patients the other day?

Q. No. I'm talking about the time you spent yesterday and today. Was there separate --

A. Yes.

Q. -- time that you spent discussing just Prolift and Prolift+M that you told me about and separate time for just Prosima, or was it just all together?

A. It was in the aggregate.

Q. Are there any complications using native tissue that you do not have with vaginal mesh?

A. There could be the way I do it. For example, in the specific technique that I use with uterosacral ligaments, entrapping a nerve near one of the ligaments on one side of the pelvis occurs about one time out of 100, and I think -- I know that is specific to the technique that I use. I don't know that that occurs with either the Prolift or the Prosima. So that may be one difference.

Another difference is when I do the reconstructive surgery transvaginally, I frequently use

some sutures which do not dissolve -- not all, but I use some Ethibond sutures. Those may end up being exposed in the vaginal tissue at a time after a normally expected recovery interval of six to 12 weeks. So a patient could come back in months or, frankly, even in several years or more and say they have some vaginal spotting, and I may see a suture exposed through the vaginal skin, which almost always can be removed in the office.

There are a few exceptions where it's so high in the vaginal canal that it's better to do it with what's called local MAC anesthesia, where somebody inhales something and gets some IV sedation. So that occurs occasionally. And that's a consequence of my intentional decision to use sutures that don't dissolve.

Q. Have you ever reviewed any animal testing either on Prolift, Prolift+M, or Prosima?

MS. THOMPSON: Object to form.

A. Have I personally used it?

Q. (BY MR. WEBB) Have you personally reviewed any animal testing on Prolift, Prolift+M, or Prosima?

A. I don't think so.

Q. Would you expect a product to look different after implantation than it did when it is explanted?

A. Excuse me. Would I expect it to look

different?

Q. Would you expect a product that's been implanted to be -- to look different than that when you -- when it's explanted from the body?

A. Yes, sir.

Q. Especially something with mesh that's designed to have ingrowth into the mesh?

A. Yes, sir. It may look different from several -- for several reasons. One of them could be adjacent tissue. One could be a change in the geometry or the surface area of the product.

Q. Do you consider it the responsibility of a surgeon to keep current on the medical literature in their area of expertise or their area of practice?

A. Yes, sir.

Q. Did Ethicon tell the doctors in the instructions for use document for Prosima that training on the use of Prosima was recommended and available?

A. I believe the wording would be you could request it -- yes, it was available if you wanted it. I don't think it was indicated it was required, but it was -- if you wanted it, it was available.

MR. WEBB: I'll pass the witness.

EXAMINATION

BY MS. THOMPSON:

Q. I have a few questions, Dr. Shull.

When you asked for the literature regarding Prolift and Prolift+M, did you ask for all of the literature available?

A. Yes, I did.

Q. And is the same true for Prosima?

A. Yes, I did.

Q. And did you personally review and critically assess this literature?

A. Yes, I did.

Q. Were you aware of any kind of screening process that was used to select the articles that we -- were sent to you?

A. No, I'm not. I wasn't.

Q. And did the literature that you reviewed and critically assessed, did it include literature that, at least from the author's conclusions, were both favorable and unfavorable to your opinions?

A. Yes. I think in every one I read, the authors found something positive to say about the products, and in every one I read, particularly in the discussions, there was information to say there -- there needed to be longer follow-up, and there are other items that could

be learned about.

Q. You were asked questions about your experience with mesh complications. Are your colleagues and the fellows at Scott & White also seeing patients with mesh complications?

MR. WEBB: Objection.

A. Yes, they are.

Q. (BY MS. THOMPSON) And are you aware, generally, of the mesh complications that are being seen in your department by others?

A. In general, that's true. We have what's called an M&M conference every month, and we may talk about specific issues. They could be related to mesh exposure, or when we look at the operative schedule, we frequently discuss what the day is like, and we'll know that someone is going to be working on a mesh explantation, for example.

Q. And your colleagues are also removing mesh devices at Scott & White?

A. Yes.

MR. WEBB: Objection; form.

A. That's correct.

Q. (BY MS. THOMPSON) You were asked questions about whether you considered yourself an expert in certain fields. Do you remember that line of

questioning?

A. Yes, I do.

Q. As a clinician, do you have familiarity with the medical literature relating to the material and chemical properties of polypropylene mesh and their clinical significance?

A. I think I do.

Q. And are many of those articles cited in your report as providing some basis for your opinions?

A. Certainly the background information provides informed -- information for me to come to a conclusion, and I would have to look specifically at the references. Do you have one particular one in mind? I'd be glad to look at it.

Q. No. I was just speaking generally. But let's look at the -- let's look at your Prolift report, if you have that handy.

A. Well, I have the articles, including the -- I think I had some separate articles this morning. Did I leave some other articles with you this morning? May I see those just a moment -- or maybe from after lunch? Thank you.

These three articles, to ask -- to answer your question, at least in part, this article published in 2004 on "Host response after reconstruction of

abdominal wall defects with a porcine dermal collagen in a rat model" -- I beg your pardon -- that animal also had -- in addition to Pelvicol, had Prolene. So the investigators looked at a xenograft and a synthetic material and looked at a variety of microscopic parameters that could be evaluated, including inflammatory response and how fast the inflammatory response went away, and it looked at collagen deposition. So that would be in an animal model, not a human.

Q. And looking at footnotes, for example, 10, 11, 12, 13, 14 -- I'm just looking at the titles of those articles. That would be Page 7 of your report. And I see articles relating to bacterial colonization, to shrinkage, to contraction, to lightweight and large porous concepts, the material's characterization of explant polypropylene hernia meshes, the pathology of -- pathological findings of transvaginal polypropylene slings.

Are those just examples of literature that discusses the material properties of polypropylene and their clinical consequences?

MR. WEBB: Objection; form.

A. Yes.

Q. (BY MS. THOMPSON) Do you, as part of your

clinical practice, review IFUs or instructions for use for various products?

A. Yes, ma'am, particularly on the ones I use.

Q. And is the information contained in the IFU, including the warnings section, important to you and other physicians in making treatment decisions?

A. It's important in knowing globally what to expect, and ideally it should be in patient selection, for example.

Q. And is the information contained in the IFU, including the warnings, important to you and other physicians when you are obtaining an informed consent from patients?

A. Yes.

Q. Do you have an opinion as to whether the Prolift and Prolift+M devices are defective from a clinical standpoint?

MR. WEBB: Objection; form.

A. Well, from a clinical standpoint, what I see is the consequence of mesh that is -- after implantation becomes reduced in area with tight bands or exposure or tenderness to palpation, leading to clinical consequences of pain, exposure, and other issues.

So from that standpoint, I feel that I have a level of expertise for being able to obtain the

history, do the exam, and correlate the exam and the historical information.

Q. (BY MS. THOMPSON) And are those problems with the Prolift and Prolift+M devices discussed in your report?

A. Yes.

Q. And are they based on the -- your knowledge and review of the peer-reviewed medical literature as well as your experience?

A. That's correct.

Q. And would the same be true for the Prosima device?

A. In the patients in whom I have seen -- and for certain the one I've operated on -- and I don't know if I've operated on more -- yes, I have personal experience in listening to, evaluating, and managing an explant in someone with Prosima.

Q. And do the Prolift and Prolift+M devices and the Prosima behave similarly to other transvaginal polypropylene mesh kits that you're familiar with and that are reported in the medical literature?

MR. WEBB: Objection; form.

A. To the best of my knowledge, they're similar.

Q. (BY MS. THOMPSON) So literature describing complications of transvaginally placed prolapse mesh in

general would also apply to Ethicon's products?

MR. WEBB: Objection; form.

A. For the --

Q. (BY MS. THOMPSON) Is that true?

A. For the trocar-based devices, I believe that's true. For the non-trocar based, I'm not familiar that there is a another product that is similar to Prosima. There may be, but I'm not familiar with it.

Q. You were asked some questions about Ethicon's marketing to physicians. Did Ethicon market -- even if it didn't sell to physicians, did Ethicon market its products to physicians based on your review of the Ethicon documents and your knowledge of attending meetings and dealing with sales representatives of companies?

MR. WEBB: Objection; form.

A. I think I can answer it two ways. In review of the information obtained in the documents I have, it looks as if there were presentations prepared and reviewed to be able to discuss with potential customers, the doctors.

And when I go to scientific meetings, this is -- in general, whether it's an international meeting or a state or a domestic American meeting, there -- frequently, if not always, there are exhibits

that are sponsored by various companies in industry to let the registrants know what is available to be purchased.

And depending on what the product is, there may be videos. There may be demonstrations on a model of some sort, and that's particularly true of products that require surgical implantation.

In addition to having 3D models and samples of the product available for people to work with and the videos, there may be one or more physicians who have used that particular product and may lead a discussion and/or show a demonstration about how to use the products.

So I would say that those aren't -- those demonstration aren't limited to a certain segment of the people who register for the meeting -- let's use the American College of Obstetricians and Gynecologists, for example. So anyone can participate in listening to and/or perhaps even trying, on the model, different things that are being shown.

MS. THOMPSON: I have no further questions.

MR. WEBB: Let me have a follow-up here.

EXAMINATION

BY MR. WEBB:

Q. You said that -- you were asked some questions about colleagues at Scott & White who are also removing mesh devices. Do you remember that question?

A. Yes, sir, I do.

Q. Do you also have colleagues at Scott & White that are implanting mesh devices?

MS. THOMPSON: Object to form.

A. I can answer that in two ways. I have associates who do abdominal sacrocolpopexy, and they'll use a synthetic mesh for the abdominal sacrocolpopexy.

I have colleagues both in urology and GYN who may do that. I have colleagues in urology and GYN who use midurethral slings, and they're mesh products. So in those two categories, the answer is, yes, there are people who work with me who are doing that.

I don't -- to the best of my knowledge, I don't have anyone in our department who is using mesh kits transvaginally, or even the mesh applique, for prolapse. I don't think our urology group currently has.

I believe that our urology group, for which I really don't have any input on anything about it particularly -- I believe they previously had one member

who did use transvaginal mesh, but I don't know how frequently, and I don't believe that particular person works with us anything longer.

MR. WEBB: That's all I have.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: This concludes the deposition of Dr. Bob Shull. Going off the record, the time is 3:15.

(Whereupon the deposition concluded at 3:15 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

BOBBY LEWIS SHULL, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20___.

My commission expires:_____

_____

Notary Public

CERTIFICATE

I, Steven Stogel, a Certified Shorthand Reporter in and for the State of Texas, do hereby certify that BOBBY LEWIS SHULL, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.

I further certify that I am neither related to or employed by any of the parties in or counsel to this action, nor am I financially interested in the outcome of this action.

In witness whereof, I have hereunto set my hand and seal this 18th day of March, 2016.

STEVEN STOGEL

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